

AD _____

Award Number: DAMD17-96-1-6268

TITLE: "Predictors of Back Injury Among Women Military Recruits"

PRINCIPAL INVESTIGATOR: Michael T. Weaver, Ph.D.

CONTRACTING ORGANIZATION: University of Alabama at Birmingham
Birmingham, Alabama 35294-0111

REPORT DATE: November 1999

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

PII Redacted

DTIC QUALITY INSPECTED 4

20001019 117

REPORT DOCUMENTATION PAGE

*Form Approved
OMB No. 074-0188*

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.

| | | | |
|--|---|--|---|
| 1. AGENCY USE ONLY (Leave blank) | | 2. REPORT DATE November 1999 | 3. REPORT TYPE AND DATES COVERED Annual (1 Oct 98 - 30 Sep 99) |
| 4. TITLE AND SUBTITLE "Predictors of Back Injury Among Women Military Recruits" | | 5. FUNDING NUMBERS DAMD17-96-1-6268 | |
| 6. AUTHOR(S) Michael T. Weaver, Ph.D. | | | |
| 7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of Alabama at Birmingham Birmingham, Alabama 35294-0111 | | 8. PERFORMING ORGANIZATION REPORT NUMBER | |
| E-MAIL: weaverm@uab.edu | | | |
| 9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012 | | 10. SPONSORING / MONITORING AGENCY REPORT NUMBER | |
| 11. SUPPLEMENTARY NOTES | | | |
| 12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited | | | 12b. DISTRIBUTION CODE |
| 13. ABSTRACT (<i>Maximum 200 Words</i>) Military recruit training is physically demanding and results in a high rate of musculoskeletal injuries. Identification of back injury risk factors and the successful development of preventive measures could significantly decrease recruiting expenses, lost time due to back injury, and training costs for female military recruits. | | | |
| <p>The aims of this prospective, non-experimental study of female military recruits are to:</p> <ol style="list-style-type: none"> 1. Recommend exercise and educational interventions for reducing the incidence of back injury. 2. Identify risk factors for back injury and discomfort by testing (a) aerobic capacity, (b) upper body strength, (c) lower body strength, (d) functional lifting ability, (e) hamstring flexibility, (f) body composition, (g) smoking status, (h) previous back injury, (i) back knowledge, (j) life satisfaction, and (k) demographic factors. 3. Describe the distribution of types of back injuries which occur in women recruits and the basic training tasks which are leading causes of back injury in that group of recruits. <p>A convenience sample of 1200 female recruits attending basic training at Recruit Training Command, Great Lakes will be examined. Back injury and discomfort, the response variables, will be obtained from medical records and a self-report questionnaire prior to graduation.</p> | | | |
| 14. SUBJECT TERMS Women's Health | | | 15. NUMBER OF PAGES 63 |
| | | | 16. PRICE CODE |
| 17. SECURITY CLASSIFICATION OF REPORT Unclassified | 18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified | 19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified | 20. LIMITATION OF ABSTRACT Unlimited |

NSN 7540-01-280-5500

Standard Form 298 (Rev. 2-89)

Prescribed by ANSI Std. Z39-18
298-102

FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.

N/A Where copyrighted material is quoted, permission has been obtained to use such material.

N/A Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

X Citations of commercial organizations and trade names in this report do not constitute an official Department of Army endorsement or approval of the products or services of these organizations.

N/A In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and use of Laboratory Animals of the Institute of Laboratory Resources, national Research Council (NIH Publication No. 86-23, Revised 1985).

X For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

N/A In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

N/A In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

N/A In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

Mirad S. Weaver 11-Feb-2000
PI - Signature Date

Table of contents

| | |
|--|-----------|
| FRONT COVER..... | 1 |
| STANDARD FORM SF298 | 2 |
| FOREWORD | 3 |
| TABLE OF CONTENTS..... | 4 |
| INTRODUCTION..... | 5 |
| RESEARCH QUESTIONS..... | 5 |
| HYPOTHESES | 5 |
| TECHNICAL OBJECTIVES..... | 5 |
| BACKGROUND | 6 |
| <i>Physical Performance and Injury.....</i> | 6 |
| <i>Behavioral and Psychosocial Correlates of Back Injury.....</i> | 8 |
| <i>Low Back Injury in Military Recruits.....</i> | 8 |
| BODY..... | 9 |
| METHODS | 9 |
| <i>Design, Sample, and Research Setting.....</i> | 9 |
| RESPONSE VARIABLES | 10 |
| PREDICTOR VARIABLES | 10 |
| DATA COLLECTION PROCEDURES..... | 11 |
| RESULTS: NO RESULTS ARE AVAILABLE AT THIS TIME..... | 11 |
| RECOMMENDATIONS..... | 12 |
| SITE ACQUISITION..... | 12 |
| PROTOCOL REVISION | 12 |
| <i>Subject Testing.....</i> | 12 |
| <i>Data Collection.....</i> | 12 |
| SUMMARY..... | 12 |
| CONCLUSIONS: NO CONCLUSIONS ARE AVAILABLE AT THIS TIME..... | 13 |
| REFERENCES | 13 |
| APPENDICES..... | 17 |
| APPENDIX A..... | |
| <i>Data Collection Instruments</i> | |
| APPENDIX B | |
| <i>IRB Documents</i> | |
| APPENDIX C | |
| <i>One Year No-Cost Extension.....</i> | |
| APPENDIX D | |
| <i>Revised Statement Of Work.....</i> | |

Introduction

The overall goal of this study is to gain a better understanding of development of back injury in female military recruits during basic training. Just as any vigorous exercise or sports program may increase injury rates, basic training for new recruits results in a high risk for musculoskeletal injuries. Musculoskeletal injuries among recruits contributes to lost time, pain, medical costs, and even attrition. Although women recruits have been found to be at higher risk than men for some training-related injuries^{1,2}, no studies have been reported on the risks of women recruits for back injury. Therefore, an expected result of the study will be the identification of predictors of back injury which will be beneficial to the armed forces in preventing back injuries and lowering costs among women recruits. Five specific aims will be addressed toward achieving the study's overall goal:

1. To describe the incidence and prevalence of back injury in women military recruits participating in basic training.
2. To describe the distribution of types of back injuries in women military recruits participating in basic training.
3. To identify basic training tasks which are leading causes of back injury.
4. To identify physical fitness, functional lifting ability, behavioral, back knowledge, psychosocial, and demographic factors which correlate with development of back injury in women military recruits participating in basic training.
5. To identify a model which can predict the likelihood of back injury in women military recruits participating in basic training.

These aims are addressed within the following research questions (aims 1, 2, 3, and 5) and hypotheses (aim 4):

Research Questions

1. What is the incidence of back injury in women military recruits participating in basic training?
2. What is the prevalence of back injury in women military recruits participating in basic training?
3. What is the distribution of types of back injuries in women military recruits participating in basic training?
4. What basic training tasks are most frequently associated with back injury?
5. Which of the selected physical fitness, functional lifting ability, back knowledge, behavioral, psychosocial, and demographic variables are required in a logistic regression model to predict development of back injury in women military recruits participating in basic training?

Hypotheses

1. There will be significant associations between development of back injury in women military recruits participating in basic training and: (a) aerobic capacity (two mile run time), (b) upper body strength (number of push-ups and sit-ups in a two minute period), (c) lower body strength (number of squats in a one minute period), (d) functional lifting ability (floor-to-waist lift task), (e) hamstring flexibility (sit-and-reach), (f) body composition (body mass index; percent body fat), (g) smoking, (h) previous back injury, (i) back knowledge, (j) life satisfaction, (k) age, and (l) race.

Technical Objectives

Four technical objectives will be addressed within this study:

1. Measure and describe back injuries in a cohort of female military recruits undergoing basic training. This objective involves describing incidence and prevalence of back injuries and the distribution of type of back injury.
2. Describe the types of basic training activities associated with back injury.
3. Identify risk factors for back injury by testing for significant associations between development of back injury in women military recruits participating in basic training and: (a) aerobic capacity , (b) upper body strength, (c) lower body strength, (d) functional lifting ability, (e) hamstring flexibility, (f) body composition, (g) smoking, (h) previous back injury, (i) back knowledge, (j) life satisfaction, (k) age, and (l) race.
4. Develop a model to predict likelihood of developing back injury in female military recruits during basic training.

The identification of risk factors and a predictive model for back injury are the first steps required in order to develop screening and training interventions to prevent back injury. Development of successful preventive strategies could significantly decrease recruiting expenses, turn-over rates, lost time due to injury, and training costs for female military recruits.

Background

This study is guided by an injury control perspective. Within this perspective, health problems, such as back injury, are viewed as preventable if interventions are adopted which protect the individual from stressors that threaten to disrupt system stability. Requirements of basic training are considered occupational stressors which may result in back injury. The objective of this study is to identify factors which are associated with development of back injury. Once those factors are identified, preventive screening and training interventions designed to reduce risk of back injury could be incorporated into the basic training routine.

Military recruit training is physically demanding and results in excessive musculoskeletal injuries³. Vigorous exercise requirements during basic training pose risks for musculoskeletal injury among recruits, many of whom are not physically fit upon entry into military service. Despite publicity given to the hazards of deployment, recruit training and routine military work present greater continuing hazards because of the mandatory fitness testing, marching, field exercises, and frequent lifting of heavy materials⁴. Musculoskeletal injuries among recruits result in pain, lost training time, medical costs, and inability to complete training⁵. The Army reported that 9 percent of the discharges within the first six months of service were attributed to low back problems⁶. From 1990 to 1991, two-thirds (67%) of the medical discharges in the Air Force were for new recruits in basic training and resulted in cost of \$2.7 million⁷. Women recruit trainees have been found to have more lost time injuries than males in the same recruit training regimens^{1,2}. Prevention clearly is indicated to reduce musculoskeletal injuries among women recruits.

Statistics about occupational musculoskeletal injuries and back injuries are alarming. Low back injury is the leading cause of compensable injury and only the common cold results in more absenteeism in the workplace⁸. Expenditures for medical care, workers' compensation and lost work time resulting from back injury are estimated at 56 billion dollars per year⁹. Because industry is experiencing increased rates of back disabilities and is seeking ways to control these costs, the American Association of Occupational Health Nurses has identified back injury prevention research as one of its twelve priority areas¹⁰. Simultaneously the Department of Health and Human Services in Healthy People Year 2000¹¹ proposes a national health objective to increase to at least 50 percent the number of worksites which offer back injury prevention programs.

Uncertainty about the causes and pathophysiology of back injury continue to complicate efforts to control occupational back problems¹². Hypotheses about the causes of low back injury include: (a) muscle incoordination during rapid motion, (b) muscle fatigue with repetitive movements, and (c) disc degeneration from compression forces during repeated lifting^{13,14}. Risk factors which have been associated with back injury include weak lumbar and abdominal muscles, obesity, poor posture, physical stressors of heavy or frequent lifting, excessive bending, twisting or reaching, prolonged sitting or standing, vibration, smoking, age, time of day, and anxiety^{15,16,17,18,19,20,21}.

Attempts to control occupational back injury have traditionally focused on pre-employment x-rays, safety training, and strength testing²². While employers have held to the notion that x-rays may detect applicants with pre-existing back problems, empirical evidence does not support the use of x-rays for predicting the incidence of back injuries^{23,24}. In addition, pathology detected from imaging has not been found to correlate with reports of back symptoms²⁵. More recently, ergonomic task redesign to improve manual materials handling, minimize excessive loads, and alter work stations have demonstrated some success in control of back problems²⁶. Pre-placement medical screening of subjects for minimum job strength requirements has been found to be superior to a traditional medical examination in reducing the incidence of musculoskeletal problems^{27,28}. No published empirical evidence is available on the use of functional lift measures for predicting back injury among military women.

Physical Performance and Injury

Mechanical trauma is the major prevailing notion for the etiology of work-related back injury. Muscles strained by repetitive or sudden motion undergo an inflammatory response producing symptoms of pain and restricted motion. Even slight trauma limits the extent to which muscle fibers will stretch. When joints are not properly exercised and conditioned, connective tissue in tendons, ligaments, muscles, and joint capsules become dense and shortened; any attempt to regain the lost range of motion in the joint is resisted. This accounts for much of the limitation in range of motion of most joints in the body²⁹. This natural chain of events can perhaps be accelerated by repeated microtrauma

which occurs when recruits are required to participate in new physical requirements and field exercises throughout basic training.

The use of exercise for prevention of injury is based on experience in military and sports medicine. A review of military, medical, physical therapy, and sports medicine literature supports the notion that flexibility and strength training may ultimately reduce injury rates^{30,31,32,33}. Gracovetsky and Farfan³⁴ suggest that stronger trunk musculature can stabilize the spine to protect it from injurious forces. Empirical evidence indicates that sports injuries can be avoided with flexibility and strength training^{35,36}. However, participation in exercise, conditioning, and military training is known to result in injuries³. Limited data are available on the incidence of back injuries resulting from military basic training.

Lifting ability is a function of muscular strength, coordination, and flexibility. Muscular strength and flexibility maintain the spine in an erect posture and maintain equilibrium when the center of gravity shifts due to an outstretched arm or carrying a load, etc. Flexibility refers to the suppleness of a joint. With limited flexibility muscles are tight and restrict movement of the joint through the full range of motion. Lack of flexibility has been correlated with an increase in muscular injuries^{37,38}. Flexibility is accomplished with a stretching routine which serves to lengthen muscle fibers, muscle sheathing, ligamentous joint capsule, and tendons and to make them more pliable. More pliable muscles, tendons, and ligaments are less likely to be injured. Because high demand muscular activity results in microscopic muscle tears that cause the muscle to heal shorter, stretching is recommended to overcome the effects of vigorous muscular activity. Investigators attribute the back inflexibility and pain found in runners, tennis players and other athletes to this healing mechanism. Therefore, back exercises including knee to chest, trunk rotation, hamstring stretch, and press-up exercises are routinely included in exercise training to improve trunk flexibility³⁹.

Strength refers to the ability of a muscle to contract and exert power. Strength is not simply explained by the size of the muscle but is dependent on motor neuron involvement in activating the muscle fiber⁴⁰. Strength improvement requires 6-12 weeks of repetitive contractions and has been found to be due to enhanced neural activation through increase in electrical stimulation of motor units, i.e. increase in firing frequency or synchronization of firing between motor units⁴¹. Specificity of muscle groups is an essential concept in muscle training therefore to strengthen the muscles which support the back (the abdominal muscles and lumbar extensors), sit-ups and exercises such as prone isometrics are usually recommended³⁹.

Muscular demands in military work may be greater than the muscular stress of sports. Trunk mobility is essential for workplace activities such as lifting and bending⁴². Although studies demonstrated that vigorous exercise can improve trunk performance^{43,44}, numerous controversies are found in the literature regarding the value of improving mobility vs. strengthening abdominal and lumbar extensor muscles. The merits of static flexibility training, active flexibility training with or without resistance, aerobics training, or extension training are also topics of debate^{44,45,46,47}. Further research is needed to correlate lifting ability, fitness levels, and subsequent back injury rates.

Because empirical evidence has demonstrated that low back pain patients have weak abdominal and lumbar muscles and tight hip flexor, hamstring, and lower back muscles, a combination of isometric flexion, extension, and active flexion exercises are currently utilized in exercise training and exercise prescriptions³⁹. An emphasis on extension is based on observations that 1) prolonged flexion postures often result in low back pain, and 2) trunk extensor performance exceeds trunk flexor performance in subjects without back pain.

Evidence has been accumulating that workers who have insufficient strength and fitness for their jobs are likely to experience injury^{12,48,49,50}. Men and women recruits who were less physically fit on entry into military service were found to have greater lost time musculoskeletal injuries than new recruits who were physically fit¹. In a classic prospective study of 1652 firefighters Cady et al. demonstrated that exercise may have a protective effect in the prevention of back injuries⁴⁸. Increased levels of physical performance (flexibility, strength, and endurance) were associated with decreased incidence of back injury and decreased duration of back injury symptoms. In a more recent report, Cady and associates demonstrated that firefighters with better than average physical fitness as evidenced by increased flexibility or strength or work capacity had fewer back injuries than those firefighters who were less physically fit⁴⁹.

Although Cady's initial 1979 findings have been held in high regard, recent conflicting evidence has been reported and indicates the need for further research regarding functional lifting ability measures as predictors for back injury^{16,51}. In Mostardi's study, strength measured by an isokinetic lifting device was not predictive of injury in the one hundred seventy one women followed prospectively. Women in the military may be at high risk for back injury due to insufficient

strength for jobs which have been traditionally performed by men. Studies are needed which use state-of-the art physiologic back testing methods on women recruits in order to study the influence of functional lifting ability as a predictor of back injury.

Behavioral and Psychosocial Correlates of Back Injury

Cigarette smoking has been identified in a number of studies as a correlate of low back pain ^{52,53,54,55}. In one recent study the relationship between smoking status and low back pain was investigated among subjects representing 13 occupations ⁵⁶. Smoking was significantly correlated with back pain in those occupations that required physical exertion. Upon further examination, the researchers determined that smoking was more clearly related to pain in the extremities than to neck or back pain.

Only one study of military recruits has been reported which investigated the relationship between low back pain and smoking ⁶. Male recruits ($n = 160$) from a single basic training group were studied. After excluding subjects with a previous history of back pain, self-report of back pain during basic training resulted in an incidence rate of 17.0% (95% confidence interval: 11.6% - 24.1%). Two trainees were discharged from the military because of low back pain. Smoking status was significantly related to low back pain. Alcohol use, fitness level before enlistment, age, race, educational level, and work satisfaction were not significant. The investigators considered the study to be initial research on an apparently high risk population, that of military recruits. The study was limited in that no women recruits were included. Further research is indicated to ascertain if smoking is a predictor of back injury among women recruits.

Conflicting results on the relationship between obesity and low back pain have been reported. Manninen and colleagues found no correlation between body mass index and low back pain ⁵³. The one study of military trainees which examined obesity and injury, including low back injury, tendonitis, sprains, strains, and stress fractures, found no relationship between obesity and injury for women but did find this relationship among men ¹. Other investigators report positive findings. A survey of over 34,000 subjects in England reported that obesity was related to back pain at all ages ⁵⁵. In a study of nursing personnel, severity of back injury was found to be related to weight of the nurse ⁵⁷. In summary, the limited number of investigations on this association reveal only a possible relationship between low back pain and obesity at the upper quintile and fail to examine other psychosocial factors which might be confounding ⁵⁸.

Educational level, age, income, marital status, history of previous back injury, and parenthood have also been found to be related to low back pain ^{54,59,60,61}. A study of 1,149 Finnish men, followed prospectively for 3 years, revealed a fourfold risk for back injury among those with a history of low back pain ⁶². Croft and Rigby (1994) found that back pain was reported more often among women in lower income and educational levels ⁵⁹. However, in O'Connor and Marlowe's study (1993), age, race, educational level, and work satisfaction were not significant predictors of low back pain ⁶. Similarly, a population-based study of 4,000 Belgian adults did not find an association between work satisfaction and initial report of low back pain ¹². Additional studies are needed to investigate the relationship between psychosocial and demographic variables and low back pain in women. No studies of military women recruits have described the relationships between these variables and the development of back injury. For these reasons, the investigators propose to investigate multiple correlates of back injury among military women. Thus, results of this study will lead to scientific information about military women's risks for back injury.

Low Back Injury in Military Recruits

Only a few prospective studies on low back injury in military recruits have been conducted. Hellsing investigated lumbar mobility and tightness of hamstring and psoas major muscles in 999 male recruits upon enlistment in compulsory military service in Sweden and followed these recruits over four years ^{63,64}. No correlations were found between tight hamstring or psoas muscles and current back pain or the incidence of low back pain. Decreased lumbar mobility was related to current back pain at the second and third follow-up periods but was not a predictor of back injury. Clinical assessments utilizing a goniometer were the only methods of measuring mobility therefore subjectivity may have influenced the results. In addition, no women recruits were included in this study.

A recent study of male U. S. marine recruits examined the incidence of soft tissue and musculoskeletal injuries during basic training ⁵. Findings revealed a rate of 19.9 injuries per 100 recruit months. The most frequently occurring injuries were iliotibial band syndrome (22.4%), patellar tendonitis (15.1%), and low back pain (11.4%). Although the study

provided important data on the occurrence of low back injury in recruits, it failed to investigate an essential question: What are the predictors of low back injury?

Two other prospective studies on injuries in military recruits have been reported. O'Connor and Marlowe (1993) reported a low back pain incidence of 17% in their study of 160 male army basic trainees⁶. Associations between low back pain and smoking, alcohol use, fitness level, exercise frequency, emotional state, age, education, and race were examined. Smoking was the only statistically significant correlate of low back pain. A major limitation of the study was that all variables were measured by self-report. In addition, women were excluded from the study. Jones and colleagues (1993) included both males ($n = 124$) and females ($n = 186$) in their study of army recruits¹. Objective physiological measures of height, weight, body mass index, and physical performance measures of 1 mile run, number of sit-ups, and number of push-ups were investigated as possible correlates of lost time injuries. Female gender, high BMI, low running performance, and short stature for women were predictors of injury. No measures of functional lifting ability were examined as possible predictors of back injury. The investigators' finding that women recruits are at greater risk for exercise-related injury than men recruits provides support for our proposed study.

Body

Methods

This section consists of five parts: (1) a description of the design, sample and research setting, (2) a discussion of the measurement of functional lifting ability, (3) procedures for data collection, (4) data management and analysis, and (5) strengths and weaknesses of the proposed study. Data will be collected via physical performance measures, questionnaires, and use of existing medical records.

Design, Sample, and Research Setting

This study employs a prospective, non-experimental design to examine associations between back injury and selected physical performance, back knowledge, behavioral, and psycho-social factors. The sample will involve a minimum of 1200 female military recruits, of all races, who are entering basic training. The population to be studied is a normal, non-clinical population. All recruits meeting inclusion criteria will be given the opportunity to participate in the study. Subject recruitment will continue until a sample size of 1200 subjects with complete data has been realized.

Subject exclusion criteria are designed to exclude risk factors and medical conditions causing low back pain which are not related to the conditions of interest and/or which might be a contraindication to functional lifting ability testing. Subjects with the following conditions or symptoms will be excluded from participation in the study:

1. Serious underlying spinal pathology (infection, tumor, spinal stenosis, cauda equina syndrome, or other)
2. Pregnancy
3. Evidence of current urinary tract infection (by history, physical, or laboratory examination)
4. Ankylosing spondylitis, rheumatoid arthritis or other rheumatoid or connective tissue disorders

A minimum of 1200 subjects with complete data are required for this study. Originally, a sample of size 700 was estimated based on a power analysis extrapolated from results of a previous study. A recalculation of the power analysis, using a 4% injury estimate for Navy Recruits, supplied by CDR Rick Shaffer of the Naval Health Research Center, San Diego, resulted in an estimate requiring 1200 subjects. This sample size is estimated to provide a power of .95 at a two-tailed .05 significance level for Rho = .15.

In order to foster efficiency of data collection and minimize interference with recruit training, data routinely collected by the military as part of basic training (e.g.: PFT testing and computerized medical records) will be used. In the original proposal, all initial study-specific testing was proposed to be completed during medical inprocessing time within the first two days after the recruit's arrival on base. This testing includes (a) demographic and back knowledge questionnaires, (b) functional lifting ability, (c) hamstring flexibility, (d) lower body strength, and (e) skinfolds for body composition estimation. It is estimated that not more than 35 minutes of a subject's time would be taken up by this testing, of which approximately 15 minutes is needed for strength and flexibility testing. Since the questionnaires, which require approximately 20 minutes, can be completed at any time, that 20 minute time period does not have to be one contiguous

period. Measures of upper body strength, aerobic capacity, height, and weight will be obtained from the routine preliminary medical exam and fitness testing conducted on all recruits.

Timing of data collection had to be revised to fit into the recruit training schedule. Questionnaires, functional lift, flexibility, and lower body strength will be collected during the 5th week of training. Recruits are placed on work details during their 5th week, and so testing would not interfere with training activities. While this timing is not ideal in terms of the study purposes, it was the only time frame which could be arranged with the training command. In addition, any problems encountered during training would affect functional lift, strength, and flexibility results. This would provide information about areas that need additional attention for strengthening during training.

Data on numbers and types of back injury will be collected from base medical records as well as a Back Injury and Discomfort Self-Report questionnaire filled out prior to graduation. The Back Injury Self-Report questionnaire, requiring approximately 10 minutes to complete, will help to identify back pain and back injuries which interfered with recruit functioning, even though they may not have been medically treated or otherwise not recorded in the subject's medical record.

Copies of all questionnaires and data collection forms appear under Appendix A.
Response Variables

Back injury or discomfort. Occurrence of back injury or discomfort during basic training is defined as an indication on either the recruit's medical record or self-report questionnaire of an episode of lower back pain which occurred after enlistment. This data will be collected prior to basic training graduation, before medical records are pulled for future assignments.

Type of back injury. To provide consistency, Co-Investigator Dr. Michael Mueller will evaluate medical records information. Back injuries will be classified into one of three categories, based on the information obtained from the medical record and/or Back Injury Self-Report Questionnaire:

1. **Nonspecific acute low back pain.** Acute or subacute low back pain beginning after enlistment localized to the lumbosacral region, with or without radiation to the thigh, but without radiation below the knee.
2. **Acute low back pain with sciatica.** Acute low back pain beginning after enlistment localized to the lumbosacral region with radiation of pain below the level of the knee on straight leg raising.
3. **Low back pain due to major trauma.** Low back pain due to major trauma resulting in fracture or dislocation, occurring after the date of enlistment.

Predictor Variables

Aerobic capacity is defined as time to complete a two-mile run, as administered for the Army PFT evaluation. The aerobic capacity score will be the subject's VO₂ value in ml/kg/min obtained from a nomogram using time elapsed in minutes for the subject to complete a 2-mile run on a track in basic training ³⁹. Running tests have been found to be a practical and valid means of measuring physical fitness in large groups ⁶⁵. The running test, a dynamic exercise involving large muscle groups, can reveal the individual's maximal aerobic capacity ⁶⁶. High correlations between running velocity and measured VO₂ provide the empirical physiologic basis for this test ^{39,67,68,69,70}.

Upper body strength is comprised of two measures, (a) number of sit-ups completed in two minutes and (b) number of push-ups completed in two minutes, as administered for the Army PFT evaluation. In our pilot study with fire fighters, number of curl-ups in one minute was predictive of trunk performance. Additionally, number of sit-ups in one minute was found to be associated with back pain in our study of fire fighters and police.

Lower body strength is defined as number of squats completed in a one minute time period. Subjects will be asked to stand with arms at sides and instructed to squat, bending at the hips and knees while keeping the trunk vertical. With each squat they will be asked to touch the fingertips of both hands to the floor.

Hamstring flexibility is defined as score on the Acuflex I Sit-and-Reach test. The Acuflex I Sit-and-Reach test, a commonly used flexibility test, is indicative of everyday body movements such as reaching and bending ⁷¹. The subject sits on the floor with legs fully extended, bottom of feet against the Acuflex I and toes pointed up (no shoes), and with one hand on top of the other reaches forward as far as possible to push a sliding device forward with the fingertips.

Knees should remain flat against the floor. The flexibility score is the number of inches reached on the best of three attempts.

Functional lifting ability. The floor-to waist lift task is one of 36 work-related functional tasks tested in the Physical Work Performance Evaluation⁷². This task measures a person's ability to lift progressively heavier weights from the floor to waist height. Each subject will be assessed with an empty weight receptacle to determine that she is using the best possible lifting technique. Weights are then added in five pound increments until a safe maximum is reached. Specific objective observational criteria are used to determine when a maximum level has been reached. The kappa for inter-rater reliability is .78 for this task.

Body mass index is defined as the ratio of weight in kilograms to squared height in meters⁷³. Height and weight measures will be obtained from subjects' medical records.

Percent body fat. Percent body fat will be estimated using measures of thigh (midline of anterior aspect of thigh, midway between inguinal crease and proximal border of patella), suprailiac (midaxillary line immediately superior to the iliac crest), and tricep (midline of posterior aspect of arm over triceps muscle, midway between lateral projection of acromion process of the ulna) skinfold thickness, as described by⁷⁴. Three measurements of skinfold thickness will be obtained at each anatomical site, using Lange calipers, and recorded. The average of the three values will be used to estimate percent body fat.

Back knowledge is defined as the number of correct subject responses to 13 items on spine anatomy and physiology, proper lifting, and ergonomics on the Back Knowledge Questionnaire. Six items were modifications of White's back evaluation questionnaire⁷⁵. Remaining items were investigator-developed and adapted from those used in our previous research. Content validity was assessed by a panel of three experts in the fields of ergonomics, occupational health nursing, and physical therapy. Initially our test-retest reliability was .67. Subsequent to receiving reviewers' comments, we conducted a second test-retest reliability assessment in January 1992. Test-retest reliability with a two week interval between tests was .79 on 33 maintenance workers.

Smoking is measured by self-report regarding cigarette and other tobacco use on the Demographic Questionnaire. These items are adapted from the "Good Health Program" Health Risk Appraisal Questionnaire.

Life satisfaction. Self-report regarding life satisfaction on the Demographic Questionnaire. This item is adapted from the "Good Health Program" Health Risk Appraisal Questionnaire.

Parental status. Self-report regarding whether the subject is primary caregiver for a child of six years or younger on the Demographic Questionnaire.

Education. Self-report of highest grade level completed on the Demographic Questionnaire.

Age. Calculated from self-reported date of birth, representing age at time of entry into the study.

Race. Self-report response to two items on the Demographic Questionnaire. These items are adapted from the "Good Health Program" Health Risk Appraisal Questionnaire.

Previous back injury. Demographic Questionnaire self-report of back injury prior to enlistment.

Data Collection Procedures

Data collectors will include physical therapists and graduate research assistants local to the military base. Physical therapist training for measuring functional lifting ability will be accomplished on-site by Deborah Lechner, MS, PT (physical therapist). Research assistants will be trained in administration of the hamstring flexibility and lower body strength measures, as well as use of the data collection forms. All physiologic measurements will be done under similar circumstances, with at least 15 minutes rest period between functional lifting ability and lower body strength testing. A pilot study of 10 subjects is planned to verify subject recruitment, scheduling, testing, data retrieval, and follow-up procedures. To minimize attrition, we will work closely with training personnel and subjects to schedule testing times that do not interfere with processing activities.

Results: No results are available at this time.

Recommendations

Site Acquisition

Our research protocol was reviewed by the Clinical Information Department's IRB, National Naval Hospital, Bethesda on 12 November, 1998. The subject consent form and data collection forms were revised based on the CID IRB recommendations, and staff training was held at RTC in March, 1999 to familiarize project staff with the research protocol and testing site. Before subjects could be enrolled, however, I was informed by the Clinical Information Department's IRB, National Naval Hospital, Bethesda that Naval Hospital Great Lakes (NHGL) did not have an approved DOD Assurance on file with the Clinical Investigation Program, and until that was taken care of, I could not begin enrolling subjects. CAPT Peter D. Kent, Medical Corps, United States Navy, Director, Clinical Investigation Program, was contacted to begin the process for NHGL to submit an assurance form for approval, and to see if I could help facilitate the process. A "go by" document was sent to NHGL by CAPT Kent in June of 1999. CAPT Kent received the completed document on 13 January 2000, and returned it to NHGL with comments for review at NHGL before final submission. To date (2000 - 02 - 11), CAPT Kent has not yet received the resubmission, and subject enrollment is still on hold.

In addition, subject enrollment in all federally funded projects at the University of Alabama at Birmingham was restricted by OPRR pending re-review by the UAB IRB using revised procedures. The study protocol was re-submitted for re-review, and the UAB IRB expects to have all projects re-reviewed by the end of March, 2000.

Protocol Revision

Timing of data collection had to be revised from the Year 1 protocol to fit into the recruit training schedule. Questionnaires, functional lift, flexibility, and lower body strength will be collected during the 5th week of training. Recruits are placed on work details during their 5th week, and so testing would not interfere with training activities. While this timing is not ideal in terms of the study purposes, it was the only time frame which could be arranged with the training command. In addition, any problems encountered during training would affect functional lift, strength, and flexibility results. This would provide information about areas that need additional attention for strengthening during training.

Subject Testing

We eliminated use of the B200 testing as recommended in our Year 1 report in order to simplify testing and reduce recruit testing time so as to minimize training schedule impact. In addition, the subject numbers were increased, based on power analysis results, to accommodate the lower injury rate experienced by Navy recruits in basic training compared to their Army counterparts.

Data Collection

We revised our data collection forms to make them easier for subjects and staff to use and to provide the possibility of producing forms readable by a new OCR Form Scanning system (Teleform) that was obtained by the School of Nursing. In addition, we determined that all information required for the medical records evaluation is available through the 1523 Clinic's computerized medical records system, and we can obtain that data in machine-readable form, further simplifying data collection procedures and reducing the probability for transcription errors.

Summary

Site acquisition has been a major emphasis to date for the grant. We have obtained approval and been assigned space to conduct the study at RTC Great Lakes, and conducted a research team protocol training session at RTC Great Lakes in

March of 1999. The unforeseen lack of a valid DOD Assurance for NHGL, and the time it is taking for them to complete the required document has been a major setback. If that had been in place, goals contained in the revised Plan of Work for this year could have been met. As it is, the continuing time delays have made keeping the research team intact very difficult, and has been a drain on project funds to maintain the required Program Manager in place at RTC Great Lakes. While I believe that, at this time, sufficient funds remain to collect data on approximately 900 recruits, if data collection can not be started in the very near future, the study will have to be shut down. I have been in contact with the project officer, Dr. Patricia Modrow, to keep her informed of these happenings.

Protocols have been revised to streamline testing and data entry, limit impact on recruit training, and accommodate testing subjects in a shorter time frame.

Plans for the no-cost extension year (Year 04) are to complete data collection and preliminary data analysis and reporting. A revised **Statement of Work** has been included with this report.

Conclusions: No conclusions are available at this time.

References

1. Jones BH, Bovee MW, Harris JA, Cowan DN. Intrinsic risk factors for exercise-related injuries among male and female army trainees. *The American Journal of Sports Medicine*. 1993;21(5):705-710.
2. Friedl K, Nuovo J, Patience T, Dettori J. Factors associated with stress fracture in young Army women: indications for further research. *Mil Med*. 1992;157(7):334-338.
3. Jones B, Cowan D, Tomlinson J, Robinson J, Polly D, Frykman P. Epidemiology of injuries associated with physical training among young men in the Army. *Med Sci Sports Exerc*. 1993;25(2):197-203.
4. Deen HJ, Yamodis N. Lumbar disk disease in active duty military personnel. *Mil Med*. 1989;154(10):502-504.
5. Linenger JM, West LA. Epidemiology of soft-tissue/musculoskeletal injury among U.S. Marine recruits undergoing basic training. *Military Medicine*. 1992;157(9):491-493.
6. O'Connor FG, Marlowe SS. Low back pain in military basic trainees. A pilot study. *Spine*. 1993;18(10):1351-1354.
7. Anderson ST, Charlesworth RW. Rheumatologic disease among Air Force recruits: a multimillion-dollar epidemic. *Seminars in Arthritis & Rheumatism*. 1993;22(4):275-279.
8. Frymoyer J., Mooney V. Current concepts review: Occupational orthopedics. *Journal of Bone and Joint Surgery*. 1986;68-A:486-473.
9. Andersson G, Pope M, Frymoyer J, et al: Epidemiology and cost. In Pope M, Andersson G, Frymoyer J, et al (eds.): *Occupational Low Back Pain: Assessment, Treatment, and Prevention*. St. Louis, Mosby-Year Book, 1991, p. 106.
10. Rogers B. Developing research priorities in occupational health nursing. *American Association of Occupational Health Nurses' Journal*. 1989;37(12):493-500.
11. DHHS. *Healthy people 2000: National health promotion and disease prevention objectives*. US Public Health Service. 1991.
12. Skovron ML. Epidemiology of low back pain. *Baillieres Clinical Rheumatology*. 1992;6(3):559-573.
13. Frymoyer JW, Cats-Baril W. Predictors of low back pain disability. *Clin Orthop*. 1987;221(Aug):89-98.
14. Borenstein D. Epidemiology, etiology, diagnostic evaluation, and treatment of low back pain. *Current Opinion In Rheumatology*. 1992;4(2):226-232.
15. Anderson R. The back pain of bus drivers. Prevalence in an urban area of California. *Spine*. 1992;17(12):1481-1488.
16. Battie M, Bigos S, Fisher L, Spengler D, Hansson T, Nachemson A, & Wortley M. The role of spinal flexibility in back pain complaints within industry: A prospective study. *Spine*, 1990;15 (8):768-773.
17. Bigos SJ, Battie MC, Fisher LD. Methodology for evaluating predictive factors for the report of back injury. *Spine*. 1991;16(6):669-670.
18. Frymoyer J., Gordon S. (1989). Research perspective in low back pain. *Spine*. 1989;14 (12):1384-1390.

19. Knapik J, Ang P, Reynolds K, Jones B. Physical fitness, age, and injury incidence in infantry soldiers. *J Occup Med.* 1993;35(6):598-603.
20. Pietri F, Leclerc A, Boitel L, Chastang JF, Morcet JF, Blondet M. Low-back pain in commercial travelers. *Scand J Work Environ Health.* 1992;18(1):52-58.
21. Suadicani P, Hansen K, Fenger AM, Gyntelberg F. Low back pain in steelplant workers. *Occup Med.* 1994;44(4):217-221.
22. Graveling RA. The prevention of back pain from manual handling. *Ann Occup Hyg.* 1991;35(4):427-432.
23. Bigos SJ, Battie MC, Fisher LD, Hansson TH, Spengler DM, Nachemson AL. A prospective evaluation of preemployment screening methods for acute industrial back pain. *Spine.* 1992;17(8):922-926.
24. Himmelstein JS, Andersson GB. Low back pain: risk evaluation and preplacement screening. *Occup Med: State of Art Rev* 1988;3(2):255.
25. Tsang IK. Perspective on low back pain. *Curr Opin Rheumatol.* 1993;5(2):219-223.
26. Snook, S. (1987a). Approaches to the control of back pain in industry: Job design, job placement and education/training. *Spine: State of the art reviews.* 1987a;2(1):45-59.
27. Chaffin DB. Human strength capability and low back pain. *J Occup Med.* 1974;16:248.
28. Keyserling W, Herrin G, Chaffin D. Isometric strength testing as a means of controlling medical incidence on strenuous jobs. *J Occup Med* 1980;22:332.
29. Lamb DR. *Physiology of exercise.* New York: Macmillan Publishing Co. 1984.
30. Arheim DD. *Modern principles of athletic training.* St. Louis, MO: C.V. Mosby Co. 1985.
31. Paris SV. The role of the physical therapist in pain control programmes. *Clinics Anesthesiology.* 1985;3,250.
32. Sealey DE. Practical consultation in flexibility exercises for knee and lower extremities. In L. Hunter & F. Funk (Eds.), *Rehabilitation of the injured knee.* St. Louis, MO: C. V. Mosby Co. 1984.
33. Tall RL, DeVault W. Spinal injury in sport: epidemiologic considerations. *Clin Sports Med.* 1993;12(3):441-448.
34. Gracovetsky S, Farfan H. The optimum spine. *Spine.* 1986;5:543-571.
35. Ekstrand J, Gillquist J, Liljedahl S. Prevention of soccer injuries. *American Journal of Sports Medicine.* 1983;10:75-78.
36. Wiktorsson-Moller M, Oberg B, Edstrand J, Gillquist J. Effects of warming up, massage and stretching on range of motion and muscle strength in the lower extremity. *American Journal of Sports Medicine.* 1983;11:249-252.
37. Chandler T, Kebler W, Uhl T, Wooten B, Kiser A, Stone E. Flexibility comparisons of junior elite tennis players to other athletes. *American Journal of Sports Medicine.* 1990;18:134-136.
38. Fathallah FA, Marras WS, Wright PL. Diurnal variation in trunk kinematics during a typical work shift. *J Spinal Disord.* 1995;8(1):20-25.
39. Pollock M, Wilmore J. *Exercise in health and disease.* Philadelphia: W. B. Saunders Co. 1990.
40. Jones D, Rutherford OL, Parker D. Physiological changes in skeletal muscle as a result of strength training. *Quarterly Journal of Experimental Physiology.* 1989;74:233-256.
41. Jones D, Rutherford O. Human muscle strength training: The effects of three different regimes and the nature of the resultant changes. *Journal of Physiology.* 1987;391:1-11.
42. Jackson C, Brown M. Analysis of current approaches and a practical guide to prescription of exercise. *Clinical Orthopedics and Related Research.* 1983;179(October):46-54.
43. Kahanovitz N, Nordin M, Verderame R, Yabut S, Parnianpour M, Viola K, Mulvihill M. Normal trunk muscle strength and endurance in women and the effect of exercises and electrical stimulation. Part 2: Comparative analysis of electrical stimulation and exercises to increase trunk muscle strength and endurance. *Spine.* 1987;12:112-118.
44. Pollock M, Leggett S, Graves J, Jones A, Fulton M, Cirulli J. Effect of resistance training on lumbar extension strength. *American Journal of Sports Medicine.* 1989;17:624-629.
45. Hall H. The back school. In C. Tollison & M. Kriegel (Ed.), *Interdisciplinary rehabilitation of low back pain.* Baltimore: Williams & Wilkins. 1989.
46. Kendall P, Jenkins J. Exercises for backache: A double-blind controlled trial. *Physiotherapy.* 1968;54:154-157.

47. Snyder-Mackler, L. (1989) Rehabilitation of the athlete with low back dysfunction. *Clinics in sports Medicine*. 1989;8:717-729.
48. Cady LD, Bischoff DP, O'Connell ER, et al. Strength and fitness and subsequent back injuries in firefighters. *Journal of Occupational Medicine*. 1979;21:269-272.
49. Cady L, Thomas P, Karwasky R. Program for increasing health and physical fitness of fire fighters. *Journal of Occupational Medicine*. 1985;27:110-114.
50. Tollison CD, Kriegel ML. Physical exercise in the treatment of low back pain, part 1: A review. *Orthopedic Review*. 1988;17:724-729.
51. Mostardi RA, Noe DA, Kovacik MW, Porterfield JA. Isokinetic lifting strength and occupational injury. A prospective study. *Spine*. 1992;17(2):189-193.
52. Deyo RA, Bass, JE. Lifestyle and low back pain. The influence of smoking and obesity. *Spine*. 1989;14(5):501-506.
53. Manninen P, Riihimak H, Heliovaara M. Incidence and risk factors of low-back pain in middle-aged farmers. *Occup Med*. 1995;45(3):141-146.
54. Toroptsova NV, Benevolenskaya LI, Karyakin AN, Sergeev IL, Erdesz S. Cross-sectional study of low back pain among workers at an industrial enterprise in russia. *Spine*. 1995;20(3):328-332.
55. Wright D, Barrow S, Fisher AD, Horsley SD, Jayson MI. Influence of physical, psychological, and behavioral factors on consultations for back pain. *Br J Rheumatol*. 1995;34(2):156-161.
56. Boshuizen HC, Verbeek JH, Broersen JP, Weel AN. Do smokers get more back pain? *Spine*. 1993;18(1):35-40.
57. Garrett B, Singiser D, Banks SM. Back injuries among nursing personnel: the relationship of personal characteristics, risk factors, and nursing practices. *AAOHN J*. 1992;40(11):510-516.
58. Garzillo MJ, Garzillo TA. Does obesity cause low back pain? *J Manipulative Physiol Ther*. 1994;17(9):601-604.
59. Croft PR, Rigby AS. Socioeconomic influences on back problems in the community in britain. *J Epidemiol Community Health*. 1994;48(2):166-170.
60. Finkelstein MM. Back pain and parenthood. *Occup Environ Med*. 1995;52(1):51-53.
61. Wohl AR, Morgenstern H, Kraus JF. Occupational injury in female aerospace workers. *Epidemiology*. 1995;6(2):110-114.
62. Riihimaki H, Viikari-Juntura E, Moneta G, Kuha J, Videman T, Tola S. Incidence of sciatic pain among men in machine operating, dynamic physical work, and sedentary work. A three-year follow-up. *Spine*. 1994;19(2):138-142.
63. Hellsing AL. Passive lumbar mobility. A prospective study of back pain in young men during their military service. *Upsala J Med Sci*. 1988;93(3):255-265.
64. Hellsing AL. Leg length inequality. A prospective study of young men during their military service. *Upsala J Med Sci*. 1988;93(3):245-253.
65. American College of Sports Medicine. *Guidelines for Exercise Testing and Prescription*. Philadelphia: Lea & Febiger, 1986.
66. Leff A. *Cardiopulmonary exercise testing*. Orlando: Grune & Stratton. 1986.
67. Cooper K. A means of assessing maximal oxygen intake. *Journal of the American Medical Association*. 1968;203(3):135-138.
68. Cooper K. *The aerobic way*. New York: M. Evans and Company. 1977.
69. National Center for Health Statistics. *Assessing physical fitness and physical activity in population-based surveys*. Dhhs Pub. No (PHS) 89-1253. Washington: U. S. Government Printing Office. 1989.
70. Skinner J. *Exercise testing and exercise prescription for special cases*. Philadelphia: Lea & Febiger. 1987.
71. Hoeger W, Hopkins D, Johnson L. *Assessment of muscular flexibility*. Addison, Illinois: Novel Products. 1988.
72. Lechner D. Work technology review: Smart-LiftSM. *Work: A Journal of Prevention, Assessment & Rehabilitation*. 1994;4:223-225.
73. Keys A, Fidanza F, Karvonen M, Noboru K, Taylor H. Indices of relative weight and obesity. *Journal of Chronic Diseases*. 1972;25:329-343.

74. Jackson AS, Pollock ML, Ward ML. Generalized equations for predicting body density of women. *Med Sci Sports Exercise*. 1980;12, 175-.
75. White A. *Back school and other conservative approaches to low back pain*. St. Louis: C. V. Mosby Company. 1983.

Appendices

Appendix A
Data Collection Instruments



Draft

Predictors of Back Injury & Discomfort Among Women Military Recruits

Demographic Questionnaire Page 1

INSTRUCTIONS: Use a black pen.

Shade circles like this: 

Not like this:  

For optimum accuracy, please print carefully
and avoid contact with the edges of the box.
The following will serve as an example:

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|

For optimum accuracy, please print in capital letters and avoid contact with the edge of the box. The following will serve as an example:

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U | V | W | X | Y | Z |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

ID Number

Today's Date

| | | | |
|--|--|--|--|
| | | | |
|--|--|--|--|

| | | | | | | | | |
|--|--|---|--|--|--|---|--|--|
| | | / | | | | / | | |
|--|--|---|--|--|--|---|--|--|

The following questions tell us something about yourself, and your medical history. Please fill in bubble that best describes your answer to the question.

1. What is the highest grade you completed in school?

- Grade School or less
- Some High School
- High School Graduate
- Some College
- College Graduate
- Post Graduate or Professional Degree

2. Are you currently:

- Never Married
- Married
- Divorced
- Separated
- Widowed

3. What is your race?

- Aleutian, Alaska Native, Eskimo, or American Indian
- Asian
- Black
- Pacific Islander
- White
- Other

4. Are you of Hispanic origin?

- Yes
- No

5. Do you currently have a child or children under the age of six for which you are the primary care giver?

- No
- Yes, 1 child
- Yes, 2 children or more



Draft

Predictors of Back Injury & Discomfort Among Women Military Recruits

Demographic Questionnaire

Page 2

6. Are you currently pregnant?

- Yes
- No
- Don't know

ID Number

| | | | |
|--|--|--|--|
| | | | |
|--|--|--|--|

7. Do you now have a bladder infection or any symptoms of a bladder infection (for example, burning on urination, frequent urination)?

- Yes
- No

8. Do you have now or have you had a serious problem with your spine (for example, deformity, infection, tumor, herniated disk, narrowing, arthritis or other diseases)?

- Yes
- No

9. Do you have now or have you had rheumatoid arthritis or other disease of your bones or joints?

- Yes
- No

10. Do you currently have back discomfort?

- Yes
- No (Go to question # 12)

11. If you are currently having back discomfort, is it located higher than mid-way between your waist and shoulders?

- Yes
- No

12. Have you had lower back discomfort in the past?

- Yes
- No (Go to question # 21)

13. Have you ever had back surgery?

- Yes
- No

14. Have you ever received medical treatment for back discomfort?

- Yes
- No

15. Have you ever missed work or school because of back discomfort?

- Yes
- No

16. Do you still have lower back discomfort occasionally?

- Yes
- No (Go to question # 21)

17. If you still have back discomfort occasionally, how long ago did the problems first start?

years:

| | |
|--|--|
| | |
|--|--|

months:

| | |
|--|--|
| | |
|--|--|



Draft

Predictors of Back Injury & Discomfort Among Women Military Recruits

Demographic Questionnaire Page 3

ID Number

| | | | |
|--|--|--|--|
| | | | |
|--|--|--|--|

18. If you still have back discomfort occasionally, did the discomfort start with an injury at work?

- Yes
- No

19. If you still have back discomfort occasionally, have you received any medical treatment for it in the past year?

- Yes
- No

20. If you still have back discomfort occasionally, do you do any exercises now to strengthen your back?

- Yes
- No

21. How would you describe your cigarette smoking habits?

- Never Smoked
- Used to Smoke
- Still Smoke

22. If you still smoke: How many cigarettes a day do you smoke? (Fill in number):

| | |
|--|--|
| | |
|--|--|

23. If you used to smoke: How many years has it been since you smoked cigarettes fairly regularly?

(Fill in number):

| | |
|--|--|
| | |
|--|--|

years.

24. Prior to enlisting, in an average week, how many times did you participate in a sport or activity that required vigorous physical activity? Lively physical activity is exercise which lasted at least 20 minutes without stopping and was hard enough to make you breathe heavier and your heart beat faster.

- Less than 1 time per week
- 1 or 2 times per week
- At least 3 times per week

25. Thinking back on previous jobs you have had, in general, how satisfied with your jobs were you?

- Mostly satisfied
- Partly satisfied
- Not satisfied

INSTRUCTIONS: Use a black pen.

Shade circles like this: ●

Not like this: ☒ ✓

**For optimum accuracy, please print carefully
and avoid contact with the edges of the box.
The following will serve as an example:**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|

For optimum accuracy, please print in capital letters and avoid contact with the edge of the box. The following will serve as an example:

| | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U | V | W | X | Y | Z |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

ID Number

Today's Date

| | | | |
|--|--|--|--|
| | | | |
|--|--|--|--|

| | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|
| | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|

The following questions are about back health care. On each question, please fill in the bubble that you believe is the best answer.

1. Which factor is the most important for prevention of back injury:
 - having machines to do your work for you
 - exercise, correct lifting techniques, proper nutrition, and good posture
 - having an excellent doctor and proper medication

2. The bony spine is supported and kept erect by:
 - blood vessels
 - muscles and ligaments
 - nerves

3. There are nerves coming out above or below each vertebra in the spine. These nerves can lead to pain if:
 - they are irritated or inflamed
 - they have pressure on them caused by bulging disks
 - both of the above

4. Which of the following is not helpful in reducing back injury:
 - when the load is heavy or large, get assistance when possible
 - use a step or platform to keep from lifting above shoulder level
 - when a load can be pushed or pulled, pull the load with a rounded back

5. Which one of the following is most likely to cause back injury:
 - sitting
 - lifting with bent knees
 - twisting the back while lifting

6. During lifting a moderately heavy object, the knees should be:
 - one knee bent, the other straight
 - both bent
 - both straight



Predictors of Back Injury & Discomfort Among Women Military Recruits

Back Knowledge Questionnaire Page 2

7. When lifting, the optimal position for the low back is:

- arched
- flattened out
- neutral (somewhere between fully arched & fully flattened out that feels comfortable)

ID Number

| | | | |
|--|--|--|--|
| | | | |
|--|--|--|--|

8. When pulling a heavy object, which muscles should do the most work:

- arm muscles
- leg muscles
- back muscles

9. When pulling a heavy object, a person should:

- arch the back to support the object
- angle the body around the object
- try to maintain the back in a neutral position

10. When lifting you should:

- hold the load as close to the body as possible
- not twist the back
- both of the above

11. When bending over to pick up a heavy object:

- squat down, keeping the back in a neutral position
- squat down, arching the back
- lock your knees

12. To keep the load close and maintain good balance during lifting:

- keep your feet close together and reach out over your knees to get the load
- keep your feet apart and get the load in between your knees
- lean backwards and hold your head back

13. When carrying a load upstairs you should:

- carry the load with a bent back to relieve muscles
- face forward with your head in neutral position, glancing down with eyes to watch steps from time to time
- look down at your feet and turn to look behind you every few steps

14. When pulling an unconscious or injured person away from danger you should:

- face the victim and pull as you walk backward, keeping your back as straight as possible
- twist your back to turn in the direction you are going while pulling the victim
- both of the above

15. When lifting, your stomach muscles should be:

- fully relaxed
- fully tightened, while holding your breath
- somewhat tightened, while breathing normally

Thank you for your willingness to participate in this study!

Predictors of Back Injury & Discomfort Among Women Military Recruits Physical Therapist Evaluation of Lifting Technique with Empty Box

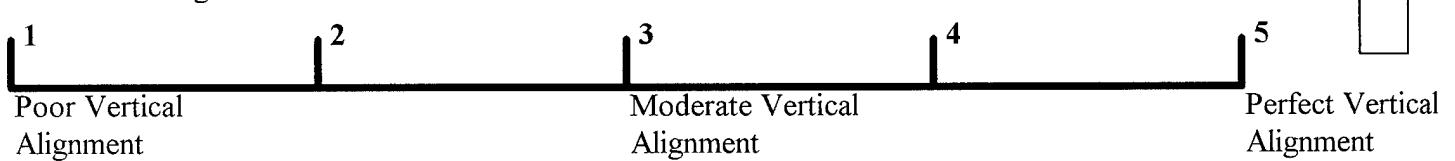
ID Number

Today's Date

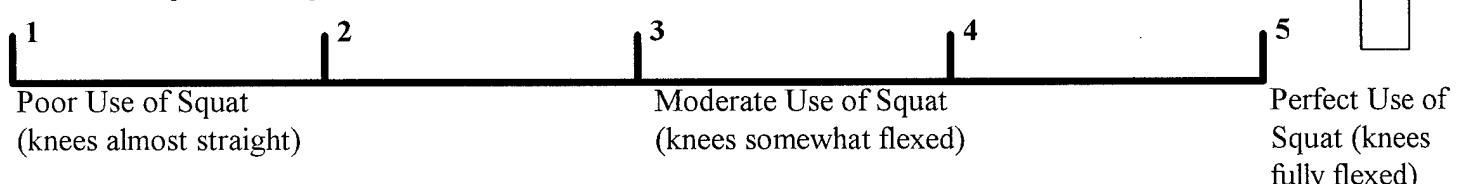
_____ / _____ / _____

Physical Therapist

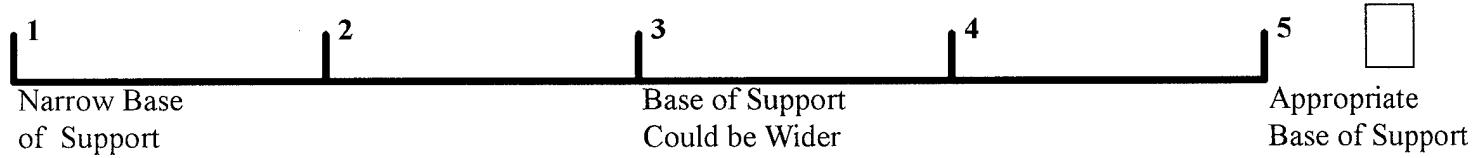
1. Vertical alignment of trunk



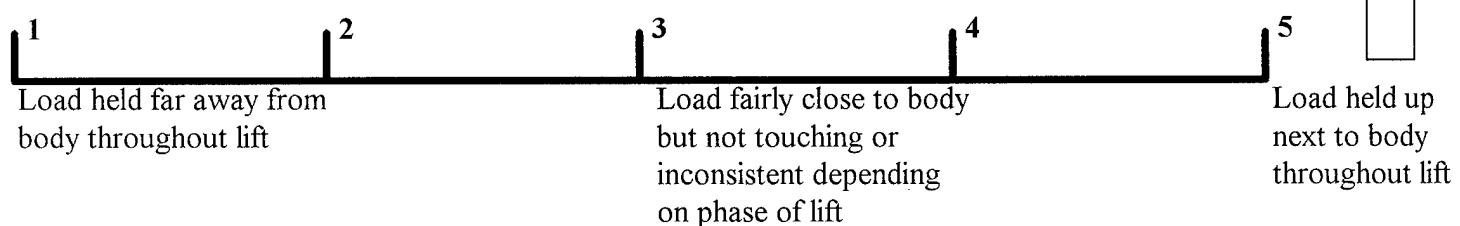
2. Use of squat technique



3. Base of support



4. Distance of load from body



Total Score

ANSWER

Needs further instruction? Yes No



18789

Predictors of Back Injury & Discomfort Among Women Military Recruits Physical Therapist Evaluation of Floor to Waist Lift

ID Number

| | | | |
|--|--|--|--|
| | | | |
|--|--|--|--|

| Rep | Weight | Time | HR | Pain Rating | Location | Evidence of Max | SAS |
|-----|--------|------|----|-------------|----------|-----------------|-----|
| 0 | 1 | | | | | - | |
| 0 | 2 | | | | | - | |
| 0 | 3 | | | | | - | |
| 0 | 4 | | | | | - | |
| 0 | 5 | | | | | - | |
| 0 | 6 | | | | | - | |
| 0 | 7 | | | | | - | |
| 0 | 8 | | | | | - | |
| 0 | 9 | | | | | - | |
| 1 | 0 | | | | | - | |
| 1 | 1 | | | | | - | |

Limiting Factor(s): (What made this task difficult for you?)

SCORING CRITERIA

Position for Observation: Sagittal Plane (either side)

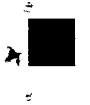
Sub-Max:(SM) No signs of Near-Max

Near-Max Effort: (NM)

1. Face Red/Perspiration
 2. Accessory Muscles
 3. Post Trunk Lean
 4. Elbow Extension
 5. Hands Slip/Difficulty Holding Box
 6. Decreased Box Control
 7. Shaking/Quivering
 8. Raises on Tip Toe
 9. Increased Time to Complete Repetitions
 10. Vertical Trunk Alignment Decreases
 11. Props Box on Thigh
 12. Irregular Steps
 13. Increased Thoracic Kyphosis with Protraction of the Shoulder Girdle
 14. Other _____

Maximal Effort:(M)

1. Completes lift but intensity of near-max signs increases - unsafe
 2. Completes lift but new near-max signs appear - unsafe
 3. Unable to complete lift:
 - a. unable to lift from floor
 - b. unable to lift to waist
 - c. unable to rise from squat



Draft



Predictors of Back Injury & Discomfort Among Women Military Recruits Physical Performance Information Form

ID Number

| | | | |
|--|--|--|--|
| | | | |
|--|--|--|--|

Number of squats in 60 seconds

| | |
|--|--|
| | |
|--|--|

Trial #1

| | |
|--|--|
| | |
|--|--|

Trial #2

| | |
|--|--|
| | |
|--|--|

Sit-And-Reach (Inches from 0)

PFT Testing Date (MM/DD/YY)

| | | | | | | | |
|--|--|---|--|--|---|--|--|
| | | / | | | / | | |
|--|--|---|--|--|---|--|--|

1.5-Mile Run Time (MM:SS)

| | | | | |
|--|--|---|--|--|
| | | : | | |
|--|--|---|--|--|

Number of Push-ups In Two Minutes

| | | |
|--|--|--|
| | | |
|--|--|--|

Number of Sit-ups In Two Minutes

| | | |
|--|--|--|
| | | |
|--|--|--|

Percent Body Fat

| | |
|--|--|
| | |
|--|--|





25808

Predictors of Back Injury & Discomfort Among Women Military Recruits

Back Injury & Discomfort Self-Report Questionnaire

ID Number

| | | | |
|--|--|--|--|
| | | | |
|--|--|--|--|

Today's Date

| | | | | | | | | | | |
|--|--|--|--|---|--|--|--|---|--|--|
| | | | | / | | | | / | | |
|--|--|--|--|---|--|--|--|---|--|--|

Please answer the following questions regarding any back problem you may have had during basic training:

1. Did you experience any back injury or discomfort not caused by your menstrual period, during basic training?

- Yes (Go to question #2)
 No (STOP: Thank you for participating in this study!)

2. Did the back injury or discomfort make it harder to perform any basic training activities?

- Yes (Go to Question #3)
 No (STOP: Thank you for participating in this study!)

3. How many times did you experience back injury or discomfort during basic training that made it harder to perform the basic training activities?

| | |
|--|--|
| | |
|--|--|

times.

For questions 4-10, please think about the back injury or discomfort that caused you the **MOST PROBLEMS** during basic training:

4. What caused you to experience the back discomfort (Example: Lifting field pack off ground.)?

Code

| |
|--|
| |
|--|

5. Where was the discomfort located?

- Below the middle of the back Above the middle of the back

6. How severe was the discomfort?

- Mild Moderate Severe

7. How did the discomfort feel?

- Dull Sharp

8. Did you experience pain or discomfort in

- Back only Back and running down to knee Back and running down to foot

9. Did you report the back injury or discomfort to the medical clinic?

- Yes No

10. Were you placed on limited or restricted duty due to the back discomfort?

- Yes (Go to Question #11) No (STOP: Thank you for participating in this study!)

11. How long were you placed on limited or restricted duty due to the back discomfort?

| | |
|--|--|
| | |
|--|--|

 days.

Thank you for participating in this study!

Appendix B

IRB Documents



Provost Office

January 20, 2000

M E M O R A N D U M

To: Michael T. Weaver
From: Joan F. Lorden, Ph.D.
Subject: Restriction of Multiple Project Assurance M-1149

Please accept this memo as confirmation that United States Army has been notified of the above referenced restriction for your active federal project entitled "*Predictors of Back Injury Among Women Military Recruits*", sponsor award number DAMD17-96-1-6268.

Office of Grants and Contracts Administration
1170 Administration Building
701 20th Street South
205.934.5266
Fax 205.975.5977

Mailing Address:
AB 1170
1530 3RD AVE S
BIRMINGHAM AL 35294-0111

UNIVERSITY OF ALABAMA AT BIRMINGHAM - INSTITUTIONAL REVIEW BOARD
INVESTIGATOR'S PROGRESS REPORT - FULL REVIEW

(PLEASE TYPE)

Principal Investigator Michael T. Weaver Today's Date 12/14/99
Address: NB 231 Contact Person Thomas Kekes-Szabo Phone Number 5-8956

Protocol Title:

Predictors of Back Injury among Women Military Recruits

1. Briefly describe the purpose of the study (2-3 sentences).

The aim of the study is to describe the incidence and prevalence of back injury in female military recruits.

2. Starting Date of Project: 10/01/96 Date of Last Approval by IRB 9/25/98

3. a. How many subjects* have been screened for study entry since the start of the project? 0
b. How many subjects* have been entered into the study since the start of the project? 0
c. How many subjects* have been entered into the study since the last IRB review? 0
d. Describe the gender and racial/ethnic composition of the study subjects. N/A

*For projects being conducted at multiple institutions, the numbers stated should be for subjects entered at UAB.

4. State any side effects or untoward events that have occurred. Summarize reports submitted since last review.

Data collection has not started yet.

5. Have you had any problems obtaining informed consent?

No.

6. a. Have you made modifications to the protocol which affect the subject? Yes No x.

If yes, have the changes been approved by the IRB? Yes No .

- b. State any changes to the protocol and/or consent form you wish to request at this time. Attach the revised consent form, if applicable, with the changes highlighted.

None

7. What are your plans for future participant enrollment?

Data collection start date is pending upon Navy approval.

8. What preliminary findings or evaluations of the study have you received? State both the positive and negative results received at this time.

N/A

Attach to this Progress Report a copy of your current consent form and a copy of a memo from your Project .

Review Panel addressing the following questions:

1. Has the Panel's assessment of the risk-benefit ratio of this project changed? If yes, please explain.

2. Does the Panel have any recommendations regarding the protocol or the consent form?

M E M O R A N D U M

TO: Chairman, Institutional Review Board

FROM: Michael T. Weaver

DATE: December 14, 1999

RE: Review of "Predictors of Back Injury in Female Military Recruits"

This is to inform you that the Project Review Panel's assessment of the risk-benefit ratio of this project has not been changed. Furthermore, the Panel does not have any new recommendation regarding the protocol or the consent form.

Thank you very much for your review of this application.

Michael T. Weaver

Michael T. Weaver, Ph.D., R.N.
Associate Professor, Principal Investigator

Ann J. Clark

Ann J. Clark, Ph.D., R.N.
Associate Professor, Panel Member

Anne Turner-Henson

Anne Turner-Henson, DSN, R.N.
Associate Professor, Panel Member

Joan G. Turner

Joan G. Turner, DSN, R.N.
Professor, Panel Member

NATIONAL NAVAL MEDICAL CENTER
BETHESDA, MARYLAND

Consent for Voluntary Participation in a Clinical Investigation Study

1. I, ., have been asked to voluntarily participate in a research project entitled, "Predictors of Back Discomfort or Injury among Women Military Recruits" being conducted at the Great Lakes Naval Recruit Training Center, Chicago, Illinois. This study is sponsored by the Department of Defense through a grant to the University of Alabama at Birmingham (UAB).
2. The purpose of this research project is to learn more about factors which can lead to back discomfort or injury during basic training.
3. I understand my participation in this research project will be for a period of eight weeks.
4. If I decide to participate, I will be asked to fill out questionnaires on personal information, medical history, and back health care at the beginning of the study, and a brief questionnaire on back discomfort or injury prior to my graduation from basic training. I will also be asked to participate in tests of my strength, flexibility, body composition, and functional lifting ability. I understand that participation in this study includes giving my permission for the investigators to look at my Physical Fitness Training (PFT) tests results, and look at my medical records in order to record information related to any Back Discomfort or Injury which happened during basic training.
5. Specifically, I am aware that the experimental part of this research will help the Navy know more about factors which increase the chance of back discomfort or injury in women recruits.
6. A total of 1,200 subjects are expected to participate in this project.
7. I understand that there is a risk of injury and muscle discomfort, such as muscle sprain or strain. I understand that the risks for injury or discomfort are like what I would experience during routine exercise. I understand that during each test and exercise, I will be responsible for judging my level of discomfort and deciding how much effort to use. The time of strength and flexibility testing will be scheduled ahead of time so that I can be ready for the testing.

I understand and accept these risks.

Subject Initials

8. I understand that the research may or may not help me personally but that the results may help the investigator learn about factors which increase the chance of back discomfort or injury in women recruits and aid in the treatment of other patients.
9. I understand that this project is not designed to treat any medical condition that I may have, therefore, there is no alternative procedure course of treatment that would be advantageous to me.

UAB-IRB
Consent Form Approved 09-25-98
Expiration Date 12-10-98

10. I am aware that this study may involve risks to me (or to the embryo or fetus, if I become pregnant) which are currently unforeseeable. I am aware that I should promptly advise the investigator if I become pregnant or contemplate breast-feeding.

11. The investigator may terminate my participation in this project for the following reasons:

- a. Serious underlying spinal pathology (infection, tumor, spinal stenosis, cauda equina syndrome, or other)
- b. Pregnancy
- c. Evidence of current urinary tract infection (by history, physical, or laboratory examination)
- d. Ankylosing spondylitis, rheumatoid arthritis or other rheumatoid or connective tissue disorders

12. I have been informed that there will not be additional costs to me beyond those normally associated with my care at Great Lakes Naval Recruit Training Center, Chicago, Illinois, if I choose to participate in this project.

13. Any new significant finding developed during the course of the research which may affect my willingness to participate further will be explained to me.

14. In all publications and presentations resulting from this research project, my anonymity will be protected to the maximum extent possible; although, I realize that authorized Navy Medical Department personnel may have access to my research file in order to verify that my rights have been safeguarded.

15. If I suffer any physical injury as a result of my participation in this study, immediate medical treatment is available at the Great Lakes Naval Recruit Training Center, Chicago, Illinois. I understand that although no compensation is available, any injury as a result of my participation will be evaluated and treated in keeping with the benefits or care to which I am entitled under applicable regulations.

16. If I have any questions regarding this research project, I may contact Dr. Michael Weaver at (205) 934-6913. If I have any questions regarding my rights as an individual while participating in a research project at the Great Lakes Naval Recruit Training Center, Chicago, I can contact one of the Research Administrators, Clinical Investigation Department, at (301) 295-2275. They will answer my questions or refer me to a member of the Institutional Review Board (IRB) for further information. If I believe I have been injured as a result of this project I may call the legal office at (301) 295-2215.

17. I understand that my participation in this project is voluntary and that my refusal to participate will involve no penalty or loss of benefits to which I am entitled under applicable regulations. If I choose to participate, I am free to ask questions or to withdraw from the project at any time. If I should decide to withdraw from the research project, I will notify Dr. Michael Weaver at (205) 934-6913, to ensure an orderly termination process. My withdrawal will involve no loss of benefits to which I am entitled.

18. I understand that if, in the future, I am no longer eligible for health care as a Department Of Defense beneficiary, my participation in this research project does not guarantee me future medical care. I understand that if I am no longer a Department Of Defense beneficiary, I may not be able to obtain medical treatment from a Department Of Defense health care facility for any injuries or side effects that result from my participation in this research project. I may be responsible for seeking treatment elsewhere.

Subject Initials

I certify that I have read and understood all the preceding information concerning this research study and that my question(s) have been answered to my satisfaction. I have received a signed copy of this document from [redacted]

Subject Initials

Date Signed

Subject Signature

Typed Name-Status-Sponsor's SSN

Witness' Signature & Date

Investigator Signature & Date

Witness' typed Name-Rank-SSN

Investigator typed Name-Rank-SSN

PRIVACY ACT STATEMENT

1. Authority. 5 USC 301

2. Purpose. Medical research information will be collected to enhance basic medical knowledge, or to develop tests, procedures, and equipment to improve the diagnosis, treatment, or prevention of illness, injury or performance impairment.

3. Use. Medical research information will be used for statistical analysis and reports by the Departments of the Navy and Defense, and other U.S. Government agencies, provided this use is compatible with the purpose for which the information was collected. Use of the information may be granted to non-Government agencies or individuals by the Chief, Bureau of Medicine and Surgery in accordance with the provisions of the Freedom of Information Act.

4. Disclosure. I understand that all information contained in this Consent Statement or derived from the experiment described herein will be retained permanently at National Naval Medical Center, Bethesda, Maryland and salient portions thereof may be entered into my health record. I voluntarily agree to its disclosure to agencies or individuals identified in the preceding paragraph and I have been informed that failure to agree to such disclosure may negate the purposes for which the experiment was conducted.

Subject Signature

Signature of Witness

Typed Name, Grade or Rank

Date of Birth

**Protection of Human Subjects
Assurance Identification/Certification/Declaration
(Common Federal Rule)**

| | | |
|--|--|---|
| <p>Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the common rule. See section 101(b) the common rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the common rule.</p> | | <p>Institutions with an assurance of compliance that covers the research to be conducted on file with the Department, Agency, or the Department of Health and Human Services (HHS) should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency. Institutions which do not have such an assurance must submit an assurance and certification of IRB review and approval within 30 days of a written request from the Department or Agency.</p> |
|--|--|---|

| | | |
|---|--|---|
| 1. Request Type | 2. Type of Mechanism | 3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No. |
| <input type="checkbox"/> ORIGINAL | <input type="checkbox"/> GRANT <input type="checkbox"/> CONTRACT <input type="checkbox"/> FELLOWSHIP | |
| <input type="checkbox"/> FOLLOWUP | <input type="checkbox"/> COOPERATIVE AGREEMENT | |
| <input type="checkbox"/> EXEMPTION | <input type="checkbox"/> OTHER _____ | |
| 4. Title of Application or Activity Predictors of Back Injury Among Women Military Recruits | | 5. Name of Principal Investigator, Program Director, Fellow, or Other Michael T. Weaver |

6. Assurance Status of this Project (Respond to one of the following)

This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance identification no. M-1149 IRB identification no. 01NR

This Assurance, on file with (agency/dep) _____, covers this activity.
Assurance identification no. _____ IRB identification no. _____ (if applicable).

No assurance has been filed for this project. This Institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph _____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

This activity has been reviewed and approved by the IRB in accordance with the common rule and any other governing regulations or subparts on (date) 1-12-2000 by: Full IRB Review or Expedited Review

This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the common rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

| | |
|---|--|
| 9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed and certification will be provided | 10. Name and Address of Institution UAB 701 South 20th Street, Suite 1120 Birmingham, AL 35294-0111 |
| 11. Phone No. (with area code) (205) 934-3789 | 12. Fax No. (with area code) (205) 934-1301 |
| 13. Name of Official Ferdinand Urthaler, M.D. | 14. Title Chairman, IRB |
| 15. Signature  | 16. Date 1-12-2000 |

Authorized for local Reproduction

OPTIONAL FORM 310 (Rev. 1-98)

Sponsored by HHS/NIH

6500
Ser C10C/072

04 NOV 1999

MEMORANDUM

From: Chairperson, Institutional Review Board (IRB)
To: M. Weaver, RN, Ph.D., University of Alabama, School of
Nursing

Subj: RESULTS OF CONTINUING REVIEW AUDIT PERFORMED BY THE IRB
ON CIP STUDY #B98-095, "PREDICTORS OF BACK DISCOMFORT OR
INJURY AMONG WOMEN MILITARY RECRUITS"

Ref: (a) SECNAVINST 3900.39B
(b) NHBETHINST 3900.3B
(c) 45 CFR 46

1. In compliance with references (a) through (c), the IRB reviewed the Continuing Review findings at their meeting of 14 October 1999.

2. Committee action:

(1) You are reminded that this study is not approved by the Commander, NNMC for subject enrollment.

(2) Next Review/Audit: October 2000

(3) Level of Risk: Minimal Risk

3. For further information, please do not hesitate to contact me as the Chairperson, IRB or Ms. Sheila Gaines in the Clinical Investigation Department at (301) 295-2275.



A. DUTKA
Chairperson

Copy to:
Study File
Continuing Review Results Binder

UNIVERSITY OF ALABAMA SCHOOL OF NURSING

FACSIMILE TRANSMITTAL SHEET

| | |
|--|-------------------------------------|
| TO: | FROM: |
| Ms. Sheila Gaines | Dr. Michael Weaver |
| COMPANY: | DATE: |
| NNMC CID | 03/30/99 |
| FAX NUMBER: | TOTAL NO. OF PAGES INCLUDING COVER: |
| 301-295-1490 | 4 |
| PHONE NUMBER: | SENDER'S REFERENCE NUMBER: |
| 301-295-2275 | |
| RE: | YOUR REFERENCE NUMBER: |
| CIP # B98-095 Project DAMD 17-96-1-6368 | |

URGENT FOR REVIEW PLEASE COMMENT PLEASE REPLY PLEASE RECYCLE

NOTES/COMMENTS:

Attached please find the following: (1) Email dated 1 March 1999, describing remaining documentation needed for CIP # B98-095, Project DAMD 17-96-1-6368. (2) Signed Standards of Conduct form for Evan Norton and LT Jeffrey Caulk. (3) CV from Evan Norton.

I have also placed the original forms in overnight mail to your attention.

Please advise me as soon as possible if this completes the documentation required, and I have your permission to begin data collection. I would like to begin in early April, if possible.

I can be reached at: Voice: (205) 934-6913; Fax: (205) 975-6142; E-mail: weaverm@uab.edu.

Thank you!

NB231

1701 UNIVERSITY BLVD
BIRMINGHAM, AL 35294-1210

Date sent: Mon, 1 Mar 1999 07:29:50 -0800 (PST)
From: Carrie Rodriquez <c_rodriquez@yahoo.com>
Subject: DR.M Weavers project
To: KEKESST@ADMIN.SON.UAB.EDU

PLEASE FORWARD THIS MESSAGE TO DR. WEAVER.

CIP #B98-095, Projecdt DAMD 17-96-1-6368, Your project still needs the signed, completed standards of conduct form for LT J. Caulk and Evan Norton and a curriculum vitae for E.Norton.

Thank you

If you have any questions please contact HN Crawford or Helen Wolter at The Clinical Investigation Department NNMC Bethesda (301) 295-2275.

DO YOU YAHOO!?

Get your free @yahoo.com address at <http://mail.yahoo.com>

NNMC CIP STANDARDS OF CONDUCT
AND
CIP PROJECT INVESTIGATOR REPORT

Date
NEW

CIP #
CHANGE

INVESTIGATORS

WE THE INVESTIGATORS ON THE ABOVE CITED CLINICAL INVESTIGATION PROTOCOL,
HAVE READ AND UNDERSTAND THE PROVISIONS OF THE FOLLOWING INSTRUCTIONS AND REPORTS:

1. SECNAVINST 5370.2J, STANDARDS OF CONDUCT.
2. THE BELMONT REPORT, ETHICAL PRINCIPLE AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH, 8 APRIL 1979.
3. SECNAVINST 3900.39B, PROTECTION OF HUMAN SUBJECTS.

SECNAVINST 5370.2J IS REQUIRED READING FOR EACH INVESTIGATOR APPROVED TO CONDUCT RESEARCH IN THE NAVY CIP. THE BELMONT REPORT AND SECNAVINST 3900.39B MUST BE REVIEWED, IF THE PROTOCOL INVOLVES THE USE OF HUMAN SUBJECTS.
STATUS- T=Trainee S=Staff C=Civilian R=Resident

ACTION
ADD/DELETE/CHANGE (Circle One)
PI/AI (Circle One) **PII Redacted**
NAME Evan Norton
RANK
PRD
STATUS Project Coordinator (C)
DUSTA
DEPT UAB School of Nursing
PHONE & PAGER # 1610) 530-4614
HOURS/WEEK 60
SIGNATURE Evan Norton
DATE 3/1/99

ACTION
ADD/DELETE/CHANGE (Circle One)
AI **SW**
NAME
RANK
PRD
STATUS
DUSTA
DEPT
PHONE & PAGER # 632-470-4614
HOURS/WEEK 40
SIGNATURE
DATE

ACTION
ADD/DELETE/CHANGE (Circle One)
PI/AI (Circle One)
NAME Jeffrey Caulk
RANK LT O-3
PRD JULY 1999
STATUS ACTIVE
DUSTA RTC G-LAKES
DEPT CISD
PHONE & PAGER # 847-688-3148
HOURS/WEEK 40+
SIGNATURE
DATE 23 MAY 99

ACTION
ADD/DELETE/CHANGE (Circle One)
AI
NAME
RANK
PRD
STATUS
DUSTA
DEPT
PHONE & PAGER #
HOURS/WEEK
SIGNATURE
DATE

- * A CURRENT CURRICULUM VITAE MUST BE SUBMITTED FOR NEWLY ADDED INVESTIGATORS.
- * IF THERE IS A CHANGE IN THE PRINCIPAL INVESTIGATOR SUBMIT A NEW CONSENT FORM WITH THE NAME AND PHONE NUMBER OF THE NEW PRINCIPAL INVESTIGATOR IN THE APPROPRIATE PARAGRAPHS.
- * IF INVESTIGATIONAL AGENTS ARE USED INCLUDE FDA 1572 SIGNED BY THE PRINCIPAL INVESTIGATOR LISTING EACH NEW INVESTIGATOR WHO WILL BE USING THE AGENTS.

Completed by Michael T. Weaver, RN, Ph.D.
Principal or Associate Investigator
Typed Name & Rank Michael T. Weaver
Signature Michael T. Weaver

Evan J. Norton
231 Bertea Street
Elmhurst, Illinois 60126

Residence (630) 530-4614

PROFESSIONAL EXPERIENCE

Health Directions, Inc./Ingalls Health System, Harvey, Illinois

(1996 - 1998)

A for-profit management and consulting subsidiary of Ingall's Health System, Harvey, Illinois servicing national and local clients to include local management service bureau managing 135 physician practices, a network of Family Care Centers and a free-standing surgery center. Responsible for strategic business development with Health Directions, Ingalls Health System and client organizations to build managed care infrastructure and marketing opportunities to increase service area and patient census.

Project Manager - Business Development

Responsible for the development, implementation and management of strategic business, marketing, and consulting initiatives for Health Directions, Inc., Ingalls Health System and client organizations. Demonstrated client activities:

- Developed Managed Care Infrastructure.
- Hospital Network Development.
- Joint Commission (JCAHO) Accreditation for Ambulatory, Home Care, and Networks.
- Developed Credentialing for multi-specialty physician panel.
- Developed Safety, Risk Management and Infection Control Departments.
- Marketing and Product Brand Development.

Joint Commission on Accreditation of Healthcare Organizations, Oakbrook Terrace, Illinois

(1991 - 1995)

A not for-profit health care accreditation organization conducting Hospital, Long Term Care, Home Health, Ambulatory Care, Laboratory, and Mental Health surveys in the United States and its territories. Responsible nationally for processing and management of 900 Hospital surveys annually.

Applications Analyst - Division of Accreditation Services

Managed 900 Hospital accounts annually in United States and its territories. Researched and evaluated service trends and hospital operations through bylaws, financial reports, marketing information, corporate affiliations and interviews for policy variance and adaptation.

- Evaluated and conducted presurvey research of clients to ensure appropriate survey team and standards composition.
- Coordinated on site survey activities with senior client executive staff.
- Managed accreditation merger, consolidation and acquisition activities to ensure certification integrity.
- Facilitated change in accreditation merger, acquisition, consolidation policies to reduced policy interpretation decisions.
- Maintained client accounts for internal and external organizations and users.

Worked with CQI and process innovation concepts as well as indicator development and outcomes measurement, statistical process controls and data aggregation.

United States Army and Army Reserves

(1989 to 1997)

Positions held in order

Observer/Controller Team Leader, Captain
Company Commander, Captain
Air Battle Management Operations Officer, 1st Lieutenant
Company Executive Officer, 2nd Lieutenant
Platoon Leader, 2nd Lieutenant

EDUCATION

Bachelor of Arts

(1990)

Western Illinois University, Macomb, Illinois

Computer Proficiency: Microsoft Word, Access, Excel, Project, Power Point, ACT, Lotus 123, and WordPerfect



January 20, 1999

Ms. Sheila Gaines
Clinical Information Department
8901 Wisconsin Ave.
Bethesda, MD 20889-5600

Dear Ms. Gaines,

Enclosed please find a packet containing materials revised in response to the memo dated 14 December, 1998, Serial # 10C/0140.

I have enclosed copies with changes underlined and highlighted as well as a clean copy of the following:

Consent Form
Proposal (I was not able to make a page-for-page change.)
Questionnaires

I have also enclosed the following requested documents:

Letter of intent from Commanding Officer, Naval Hospital, Great Lakes.

Letter of intent from medical monitor.

Curriculum Vitae from medical monitor.

Revised verification worksheet.

Revised Resource Requirements.

Impact Statement form.

I was unable to get LT Jeff Caulk's SSN for the verification worksheet. LT Caulk is the interim CISD at RTC, and will be the administrative PI for the project. I have provided him with a Standards of Conduct form for him to sign, and have requested a Curriculum Vitae from him, also, which will contain his SSN. He has promised to mail those documents to me this week, and I will forward them on to you as soon as I receive them.

Please let me know if further information or clarification is required.

I may be contacted by phone at (205) 934-6913, fax at (205) 975-6142, or by e-mail at weaverm@uab.edu.

Sincerely,

A handwritten signature in cursive ink that reads "Michael T. Weaver".

Michael T. Weaver RN Ph.D.

Associate Professor

UAB School of Nursing



(Rev 3/91)

NNMC CLINICAL INVESTIGATION RESOURCE REQUIREMENTS

NNMC # _____
(CID will provide)

1. PI Michael T. Weaver RN PhD

2. TITLE Predictors of Back Discomfort or Injury among Women Military
Recruits

3. FACILITIES AND RESOURCES REQUIRED:

a. HUMAN SUBJECTS:

| | | | | |
|---------------------|------|--------|-----------------|--------|
| <u>Experimental</u> | 1200 | Number | RTC Great Lakes | Source |
| <u>Control</u> | 0 | Number | Source | |
| <u>Minors</u> | 0 | Number | Ages | |
| <u>TOTAL:</u> | | 1200 | | |

b. ANIMAL MODEL:

| <u>Species</u> | <u>Strain</u> | <u>Sex</u> | <u>Wt/Age</u> | <u>Total No.</u> | <u>Use Rate</u> |
|----------------|---------------|------------|---------------|------------------|-----------------|
| | | | | | |
| | | | | | |

c. INVESTIGATIONAL AGENTS: Description NONE

Source

Sponsor

IND/IDE # _____
 IDC# _____

d. NATIONAL ONCOLOGY GROUP PROTOCOL: Which protocol? Not Applicable

4. ALL CIVILIAN PERSONNEL:

| <u>NAME</u> | <u>POSITION</u> | <u>HRS/WEEK</u> | <u>TOTAL HOURS</u> | <u>ANNUAL SALARY</u> |
|------------------------------|-----------------|-----------------|--------------------|----------------------|
| Michael Weaver Assoc. Prof. | 8 | 416 | | |
| Kathleen Brown Professor | 4 | 208 | | |
| Deborah Lechner Assoc. Prof. | 4 | 208 | | |
| Jim Hilyer Asst. Prof. | | 30 | | |
| Michael Mueller Asst. Prof. | | 104 | | |
| Evan Norton Pgm Coord. | 40 | 2080 | | |
| Research Assistant (TBA) | 20 | 1040 | | |
| Research Assistant (TBA) | 20 | 1040 | | |
| Physical Therapist (TBA) | | 400 | | |

5. BUDGET FOR FIRST AND SUBSEQUENT YEARS:

| <u>CATEGORY</u> <u>(EXPENSE ELEMENT)</u> | <u>YEAR</u> | <u>YEAR</u> | <u>YEAR</u> | <u>YEAR</u> |
|---|-------------|-------------|-------------|-------------|
| | <u>1</u> | <u>2</u> | <u>3</u> | <u>4</u> |
| a. Personnel (U) | | | | |
| b. Rental & Utilities (M) | | | | |
| c. Preventive Maintenance | | | | |
| Equipment (P) | | | | |
| d. Purchased Services | | | | |
| Contracts (Q) | | | | |
| e. Supplies (T) | | | | |
| f. Non-Investment | | | | |
| Equipment (W) | | | | |
| g. Investment Equipment (W) | | | | |
| h. Printing & | | | | |
| Reproduction (Y) | | | | |

NNMC CLINICAL INVESTIGATION RESOURCE REQUIREMENTS

i. Other Expenses, specify None

| | | | | |
|------------------------------|------------------|----------------------|----------------------|----------------------|
| <u>TOTAL DIRECT COSTS</u> | \$ <u>208088</u> | \$ <u> </u> | \$ <u> </u> | \$ <u> </u> |
| <u>TRAVEL (HSETC FUNDED)</u> | \$ <u>0</u> | \$ <u> </u> | \$ <u> </u> | \$ <u> </u> |

6. SOURCE OF SUPPORT:

| | | <u>Source</u> |
|---------------------------------------|--|-------------------------|
| a. [] CIP | Amount \$ | |
| b. [YES] GRANT | Amount \$ <u>208088</u> | <u>DAMD17-96-1-6268</u> |
| c. [] GIFT | Amount \$ | |
| d. [] HMJFAMM | Amount \$ | |
| | [] Adjunct Faculty, USUHS (Department of _____) | |
| | [] Guest Scientist Status | |
| | [] MOU-HIV Study | |
| e. [] OTHER | Amount \$ | |
| f. [] Only services and/or supplies: | | |

7. NONGOVERNMENT SUPPORT STATEMENT

a. Is there any support for this research being received from outside the local command (except HSETC), in any way, directly or indirectly?

1) NO YES do Q-b through Q-e.

2) If Yes, please describe: Grant # DAMD17-96-1-6268

b. Is the source providing equipment?

1) X NO YES, but declined by investigator (Documentation required).

2) YES - List and describe. Include details of custody or loan arrangements if applicable (e.g. equipment issued or given to NNMC which "loans" it to investigator). Include what happens to the equipment when the project is completed or terminated.

c. Is the source providing drug supplies, laboratory services, computer services or other nonfinancial support?

 X NO YES - List and describe if not listed below.

d. Is the source providing capitation payments or other financial support?

1. NO YES, but declined by investigator. (Documentation required).

2. X YES - Provide details of financial arrangements; i.e., who receives and disburses funds, and by whose authority.

Grant funds go to and are handled by University of Alabama at Birmingham Department of Grants and Contracts.

e. Is the source providing any other type of compensation, benefits, or reimbursements; e.g., travel to meetings.

 NO X YES - List and describe.

Reimbursement for grant-related travel to RTC Great Lakes from Birmingham, AL.

NNMC CLINICAL INVESTIGATION RESOURCE REQUIREMENTS

f. All correspondence and communications with supporting outside sources must be attached.

PRINCIPAL INVESTIGATOR

Signature

Michael T. Weaver RN PhD

Printed Name

19 Jan 1997

Date

DEPARTMENT HEAD

Signature

1/20/99

Date

8. Personnel Support.

| | <u>NAME</u> | <u>RANK</u> | <u>HOURS/WEEK</u> | <u>TOTAL HOURS</u> |
|---|-------------|-------------|-------------------|--------------------|
| PI | | | | |
| AI | | | | |
| AI | | | | |
| AI | | | | |
| Total Man Years of Support: Military _____ Civilian _____ | | | | |
| (CID will calculate) | | | | |

NNMC CLINICAL INVESTIGATION PROGRAM
VERIFICATION WORKSHEET

NNMC # _____
 Date submitted _____
 Date approved _____
 (CID will complete)

1. PI Michael T. Weaver RN Ph.D.
 2. TITLE Predictors of Back Discomfort or Injury among Women Military Recruits

3

LOCATION/DEPARTMENT School of Nursing, University of Alabama at Birmingham4. STUDY DURATION 1 Year

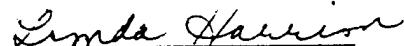
5. OTHER INSTITUTIONS (COLLABORATION) _____

6. PERSONNEL ENGAGED ON PROJECT:

| <u>NAME/GRADE</u> | <u>STATUS</u> | <u>DUTY STATION</u> |
|-------------------------------|---------------|---------------------|
| T-Trainee, S-Staff C-Civilian | | |
| PI Michael T. Weaver RN PhD | C | U. Al. Birmingham |
| API LT Jeff Caulk | | RTC Great Lakes |
| AI Kathleen Brown RN PhD | C | U. Al. Birmingham |
| AI Michael Mueller MD MPH | C | U. Al. Birmingham |
| AI Deborah Lechner PT MS | C | U. Al. Birmingham |
| AI James Hilyer EdD, MPH | C | U. Al. Birmingham |
| Evan Norton | C | RTC Great Lakes |

[X] Approved [] Disapproved


Principal Investigator's Signature
19 January 19, 1999
 Date


Department Head's Signature
1/20/99
 Date

NNMC CLINICAL INVESTIGATION PROGRAM
VERIFICATION WORKSHEET

CID STAFF WILL COMPLETE THIS SECTION:

7. RESEARCH INVOLVES:

| | <u>YES</u> | <u>NO</u> | DATE: <u>APPROVAL</u> | <u>PENDING/APPROVED</u> | <u>INITIAL</u> |
|------------------------|--------------------------|--------------------------|--------------------------|-------------------------|----------------|
| IRB | <input type="checkbox"/> | <input type="checkbox"/> | IRB | _____/_____ | _____ |
| INVESTIGATIONAL AGENTS | <input type="checkbox"/> | <input type="checkbox"/> | NIDRB | _____/_____ | _____ |
| RETROVIRUS | <input type="checkbox"/> | <input type="checkbox"/> | BUMED | _____/_____ | _____ |
| RADIOACTIVE MATERIALS | <input type="checkbox"/> | <input type="checkbox"/> | RSC | _____/_____ | _____ |
| ANIMALS | <input type="checkbox"/> | <input type="checkbox"/> | LACUC | _____/_____ | _____ |
| NONHUMAN PRIMATES | <input type="checkbox"/> | <input type="checkbox"/> | LACUC | _____/_____ | _____ |
| | <input type="checkbox"/> | <input type="checkbox"/> | BUMED | _____/_____ | _____ |
| COLLABORATION | <input type="checkbox"/> | <input type="checkbox"/> | OTHER INST | _____/_____ | _____ |

Director, CID Signature

CMDR NNMC Signature

Date

Date

Action by CO, HSETC

APPROVED _____

Signature

Date

NNMC CLINICAL INVESTIGATION PROGRAM DEPARTMENT IMPACT
STATEMENT

Study Title: Predictors of Back Discomfort or Injury among
Woman in the Military Recruits

Principal Investigator: Michael T. Weaver RN Ph.D.

Provide a statement that identifies what type of support is
needed from each Department for you to implement your
research.

Laboratory: None

Pharmacy: None

Radiology: None

Nuclear Medicine: None

Patient Administration:

Patients / # of admissions: 1200 Females

Bed occupancy and duration of stay: Not Applicable

Others:

Approvals:

Lynda Harrison

Investigator's Department Head

Name: Lynda Harrison RN Ph.D.

Rank: N/A

Title: Associate Dean

IMPACT SIGNATURES: Specify any difficulties your Department
may have in providing the support requested.

None anticipated.

Jeff Caulk 5/20/98

Name: Jeff Caulk

Rank: LT

Title: CISO

Name:

Rank:

Title:



DEPARTMENT OF THE NAVY
RECRUIT TRAINING COMMAND
NAVAL TRAINING CENTER
GREAT LAKES, ILLINOIS 60088-5300

1513
Ser 0040012
JAN 18 1999

Mr. Michael T. Weaver
University of Alabama at Birmingham
School of Nursing
1701 University Blvd.
Birmingham, AL 35294-1210

Dear Dr. Weaver:

I hereby acknowledge that I am aware of and approve of the study detailed in NNMC Clinical Investigation: Predictors of Back Discomfort or Injury among Women Military Recruits of 11 Jan 99. Further, I understand the study will occur pursuant to human test subject approval of Naval Hospital, Great Lakes

Sincerely,

A handwritten signature in black ink, appearing to read "C. I. HANSON".

C. I. HANSON
Captain, U. S. Navy
Commanding Officer

NNMC CLINICAL INVESTIGATION PROGRAM DEPARTMENT IMPACT
STATEMENT

Study Title: Predictors of Back Discomfort or Injury among Woman in the Military Recruits

Principal Investigator: Michael T. Weaver RN Ph.D.

Provide a statement that identifies what type of support is needed from each Department for you to implement your research.

Laboratory: None

Pharmacy: None

Radiology: None

Nuclear Medicine: None

Patient Administration:

Patients / # of admissions: 1200 Females

Bed occupancy and duration of stay: Not Applicable

Others:

Approvals:

Lynda Harrison

Investigator's Department Head

Name: Lynda Harrison RN Ph.D.

Rank: N/A

Title: Associate Dean

IMPACT SIGNATURES: Specify any difficulties your Department may have in providing the support requested.

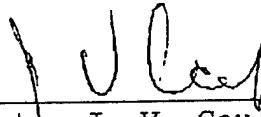
None anticipated.



Name: C. T. Harrison

Rank: CAPT

Title: Commanding Officer



Name: J. V. Caulk

Rank: LT

Title: CISO

Lieutenant Jeffrey V. Caulk U.S. Navy

Lieutenant Jeffrey Caulk was born in Thousand Oaks, CA and raised in Ontario, CA. He earned his undergraduate degree in Economics from the University of California at Los Angeles while a scholarship student in the Naval Reserve Officer Training Corps (NROTC) program, and was commissioned in December of 1990.

Lieutenant Caulk attended Basic Naval Flight Officer (NFO) Training, at Naval Air Station Pensacola, FL while attached to Training Squadron TEN from January 1991 to November 1991. He then attended Advanced Naval Flight Officer Training (Props) at Mather Air Force Base, CA from November 1991 to July 1992. Lieutenant Caulk was designated a Naval Flight Officer on July 18, 1992. Following designation, he transferred to the Fleet Replenishment Squadron, Patrol Squadron THIRTY, Naval Air Station Jacksonville, FL for training as a P-3C Orion Update III Navigator/Communicator (NAV/COMM) from July 1992 to January 1993.

Lieutenant Caulk's first assignment was to patrol Squadron FIVE (VP-5) at Naval Air Station Jacksonville, FL from January 1993 to Jul 1996. During his three and one-half year tour Lieutenant Caulk operated throughout the North Atlantic, Baltic, Adriatic, Mediterranean, Caribbean, and Eastern Pacific theaters. During three deployments he participated in numerous joint and independent operations, including ABLE MANNER, SHARP GUARD and GREEN CLOVER. He became VP-5's first NAV/COMM to serve as part of the Chief of Naval Operations' Special Project BEARTRAP, and was instrumental in developing the training program for follow on aircrews. While Mission Commander of Combat Aircrew FIVE operating from Howard Air Force Base, Panama, Lieutenant Caulk's crew had the highest drug arrest and seizure rate of any deployed P-3C aircrew. While serving in VP-5, he held billets as the Assistant Command Services Department Head, Communications Officer, Top Secret Control Officer, Secure Communications Account Custodian, Readiness Officer, NAV/COMM NATOPS Officer and Electrical Branch Officer. In July 1996, Lieutenant Caulk reported to Recruit Training Command, Great Lakes. He served as Ship's Officer for the USS RANGER and is currently the Division Officer for Recruit Division Commander (RDC) "C" School. He is responsible for training all incoming RDCs, providing command indoctrination for all incoming staff members, administering the enlisted sponsor program and supervising the command Classified Material Study Room.

During his Naval service, Lieutenant Caulk has earned: the Naval Flight Officer warfare qualification, and qualifications as detachment Officer in Charge, P-3C Mission Commander, Tactical Coordinator, Instructor NAV/COMM and BEARTRAP NAV/COMM. He has been awarded the Joint Meritorious Unit Award, Meritorious Unit Citation, Defense Service Medal, Armed Forces Service Medal, Sea Service Deployment Ribbon (3) and Coast Guard Operations Ribbon.

Lieutenant Caulk currently resides in Kenosha, WI.



DEPARTMENT OF THE NAVY
NAVAL HOSPITAL
3001A SIXTH STREET
GREAT LAKES, ILLINOIS 60088-5230

IN REPLY REFER TO:

5900
NH-05
Ser: 0102
20 JAN 99

From: Commanding Officer, Naval Hospital, Great Lakes, Illinois 60088
To: Chairperson, Institutional Review Board, National Naval Medical Center,
CID, 8901 Wisconsin Avenue, Bethesda, Maryland 20889-5600

Subj: LETTER OF INTENT

1. Your proposal "CIP Proposal #B98-095, "Predictors of Back Discomfort or Injury Among Women Military Recruits" is currently being reviewed by our Protection of Human Subjects Committee.
2. You will be notified when a final decision has been made.



E. C. HOLMES

20 Jan 99

MEMORANDUM

From: Head, Physical Therapy Department, Great Lakes
To: Chairperson, Institutional Review Board, National
Naval Medical Center, CID
Via: Director, Ancillary and Psychosocial Services ~~W~~
Subj: LETTER OF INTENT REGARDING CIP PROPOSAL # B98-095,
"PREDICTORS OF BACK DISCOMFORT OR INJURY AMONG WOMEN
MILITARY RECRUITS"

1. I agree to review subjects selected to participate in the above proposal for the duration of the study. Furthermore, I affirm that my PRD from Naval Hospital Great Lakes is July 2001.
2. For further information please contact me at commercial (847) 688-3754 or DSN 792-3754.

Respectfully,

M. C. Taylor

M. C. TAYLOR
LCDR, MSC, USN

19 January 1999

CURRICULUM VITAE

Mark C. Taylor
LCDR, MSC, USN

[PII Redacted]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Current Position:

Department Head
Naval Hospital Great Lakes
Physical Therapy Department
Great Lakes, IL 60088
August 1998 to Present

Education:

University of Rhode Island
Kingstown, Rhode Island
From 1972 to 1973
See list of courses

University of Vermont
Burlington, Vermont
From 1973 to 1976
Zoology
BA

Columbia University
New York, New York
From 1977 to 1978
Physical Therapy
Certificate in Physical Therapy

Florida Institute of Technology
Melbourne, Florida
From 1986 to 1989
Business
MBA

Massachusetts General Hospital Institute of Health Professions
Graduate Program in Physical Therapy
Boston, MA 02114
From 1996 to 1998
Master of Science in Physical therapy

Continuing Education:

- 7/79 Basic Sports Medicine and Athletic Training
Boston, Massachusetts
- 4/80 Cyriad Examinations of the Lumbar Spine
Providence, Rhode Island
- 5/80 Extremity Pain and Dysfunction (Stanley Paris)
Boston, Massachusetts
- 9/80 Emergency Medical Technician Rhode Island Junior College
12/80 Warwick, Rhode Island
- 4/81 Exercise and the Cardiac Patient
Providence, Rhode Island
- 5/81 Sports Medicine
North Haven, Connecticut
- 6/83 Treatment of the Injured Athlete
Kingston, Rhode Island
- 11/84 Beginners EMG
Morgantown, West Virginia
(Sponsored by the Section on Clinical Electrophysiology)
- 4/84 Advanced EMG, April 27-29 1984
Portsmouth, Virginia
- 12/85 Shoulder Dysfunction Evaluation and Treatment
American Rehabilitation Education Network
Portsmouth, Virginia
- 2/86 Somatosensory Evoked Potentials
Portsmouth, Virginia
- 4/86 Knee Rehabilitation a clinical approach to Sports
Injuries – American Rehabilitation Education Network
Portsmouth, Virginia
- 1/87 Evaluation and Treatment of the Spine (Saunders)
Orlando, Florida
- 8/88 Musculoskeletal Screeners Course
Fort Sam Houston, Texas
- 4/92 Current concepts in examination and rehabilitation of
Orthopaedic and Sports Conditions of the knee and
Shoulder – Lahey Clinic Medical Center
Burlington, Massachusetts

- 3/92 Orthopaedic Section Home Study Course
8/92 Topic: Lower Extremity
- 1/93 Orthopaedic Section Home Study Course
6/93 Topic: Upper Extremity
- 1/93 Orthopaedic Physical Therapy Home Study Course
8/93 Topic: Lower Extremity
- 1/94 Orthopaedic Physical Therapy Home Study Course
12/94 Topic: Lumbar Spine
- 7/95 Orthopaedic Physical Therapy Home Study Course
12/95 Topic: The Wrist and Hand

Licensure Information:

Licensed in Rhode Island #00352

Employment and Positions Held:

1. Staff Physical Therapist
Rhode Island Hospital
Providence, Rhode Island
From 1978 to 1983
2. Staff Physical Therapist
Portsmouth Naval Hospital
Portsmouth, Virginia
From 1983 to 1986
3. Department Head
Physical Therapy Department
Orlando Naval Hospital
Orlando, Florida
From 1986 to 1989
4. Department Head
Physical Therapy Department
Naval Hospital Camp Lejeune
Camp Lejeune, North Carolina
From 1989 to 1991
5. Department Head
Physical Therapy Department
Naval Hospital Groton
Groton, Connecticut
From 1991 to 1996
6. Graduate Student
Post-Professional Program in Physical Therapy
Massachusetts General Hospital
Institute of Health Professions
Boston, MA 02114
From Sept 1996 to August 1998
7. Department Head
Physical Therapy Department
Naval Hospital Great Lakes
Great Lakes, IL 60088
From August 1998 to Present

Professional Societies:

Member, American Physical Therapy Association, National and State Member, Orthopaedic Section of the American Physical Therapy Association, Member United States Naval Institute

List of Courses taken at the University of Rhode Island

September 1972-May 1973

No degrees obtained

| Subject | Year | Semester Hours |
|---------|------|----------------|
|---------|------|----------------|

Chemistry

| | | |
|---------------------------------|------|---|
| 1. General Chemistry I | 1972 | 3 |
| 2. Lab for General Chemistry I | 1972 | 1 |
| 3. General Chemistry II | 1973 | 3 |
| 4. Lab for General Chemistry II | 1973 | 1 |

Biology

| | | |
|--------------------|------|---|
| 1. General Biology | 1972 | 3 |
|--------------------|------|---|

Mathematics

| | | |
|-------------------------------------|------|---|
| 1. Algebra and Trigonometry | 1973 | 3 |
| 2. Introduction to Calculus & Anal. | 1973 | 3 |
| 3. Introduction to Calculus & Anal. | 1973 | 3 |

Behavioral Science

| | | |
|-----------------------|------|---|
| 1. General Psychology | 1973 | 3 |
|-----------------------|------|---|

Other

| | | |
|---------------------------------------|------|---|
| 1. Introduction to Literature Genre | 1972 | 3 |
| 2. Fundamentals of Oral Communication | 1972 | 3 |
| 3. Elements of Economics | 1973 | 3 |

NNMC CLINICAL INVESTIGATION PROGRAM DEPARTMENT IMPACT
STATEMENT

Study Title: Predictors of Back Discomfort or Injury among
Woman in the Military Recruits

Principal Investigator: Michael T. Weaver RN Ph.D.

Provide a statement that identifies what type of support is
needed from each Department for you to implement your
research.

Laboratory: None

Pharmacy: None

Radiology: None

Nuclear Medicine: None

Patient Administration:

Patients / # of admissions: 1200 Females

Bed occupancy and duration of stay: Not Applicable

Others:

Approvals:

Investigator's Department Head

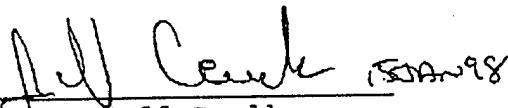
Name: Lynda Harrison RN Ph.D.

Rank: N/A

Title: Associate Dean

IMPACT SIGNATURES: Specify any difficulties your Department
may have in providing the support requested.

None anticipated.

 Jeff Caulk, FEB 1998

Name: Jeff Caulk

Rank: LT

Title: CISO

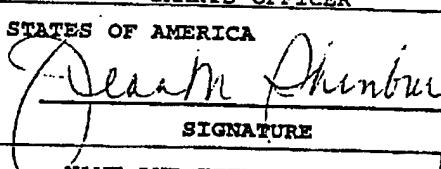
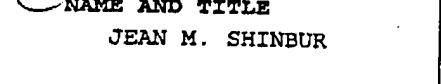
Name:

Rank:

Title:

Appendix C
One Year No-Cost Extension

ASSISTANCE AGREEMENT / FULLY EXECUTE

| | | | | | | | |
|--|--|--|--|--|--|---|--|
| AWARD TYPE: <input checked="" type="checkbox"/> GRANT (31 USC 6304) <input type="checkbox"/> COOPERATIVE AGREEMENT (31 USC 6305) <input type="checkbox"/> OTHER TRANSACTION (10 USC 2371) | | | | | | | |
| AWARD NO: DAMD17-96-1-6268 Modification No.: P00002 | | EFFECTIVE DATE See Grants Officer Signature Date Below | | AWARD AMOUNT \$260,942.00 | | Page 1 of 1 Patricia A. Shoop (301) 619-2175 | |
| PROJECT TITLE: "Predictors of Back Injury Among Women Military Recruits." | | | | | | | |
| PERFORMANCE PERIOD: 1 October 1996 - 1 November 2000 (Research Ends 30 September 2000) | | | | PRINCIPAL INVESTIGATOR: Dr. Michael Weaver | | | |
| AWARDED AND ADMINISTERED BY: U.S. Army Medical Research Acquisition Activity ATTN: MCMR-AAA-A 820 Chandler St. Fort Detrick Maryland 21702-5014 | | | | PAYMENTS WILL BE MADE BY: EFT:T Army Vendor Pay 1-888-478-5636 DFAS-SA/FPA 500 McCullough Ave. San Antonio, TX 78215-2100 | | | |
| DUNS NO: 063690705 | | | | REMIT PAYMENT TO: University of Alabama at Birmingham, Grants & Contracts Accounting ATTN: Beverly Matlock AB 990, 701 South 20th Street Birmingham, Al 35294-0109 | | | |
| ACCOUNTING AND APPROPRIATION DATA: N/A | | | | | | | |
| SCOPE OF WORK: <p>Pursuant to mutual agreement, the following changes is made in the revisions of this grant:</p> <p>The period of performance is extended without funds in order to complete the research project. Therefore, the period of performance is changed:</p> <p>FROM: 1 October 1996 - 1 November 1999 (Research Ends 30 September 1999)</p> <p>TO: 1 October 1996 - 1 November 2000 (Research Ends 30 September 2000)</p> <p>All other terms and conditions of the Grant remain unchanged.</p> | | | | | | | |
| RECIPIENT ACCEPTED BY: No Signature Required. See Grantee's Letter Dated October 29, 1999. | | | | GRANTS OFFICER UNITED STATES OF AMERICA  | | | |
| SIGNATURE | | | | SIGNATURE | | | |
| NAME AND TITLE NAME AND TITLE | | DATE | | NAME AND TITLE JEAN M. SHINBUR | | DATE  17 Nov '99 | |

Appendix D
Revised Statement Of Work

Statement of Work

Technical Objective:

Task 1: Month 1: Print & collate data collection forms, review protocol with data collectors. (Training occurred March, 1999).

Task 2: Month1: Pilot study to test procedures and reliability of measures.

Task 3: Months 2-6: Collect data on 900 female recruits undergoing basic training.

Task 4: Months 4-8: Collect medical data and post-training back injury questionnaire on 900 female recruits.

Task 5: Months 9-12: Analyze Data & begin manuscript preparation